#	Section	Commenter	Comment	Staff Response
1	General	Novo Nordisk	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 appreciates the Board's efforts to align its regulations with USP standards and to build upon those standards to further enhance the health and welfare of Californian patients who are given compounded drug products. The risks posed by compounded drugs are growing as compounders have expanded their reach by entering into new and unanticipated commercial. agreements to engage in aggressive nationwide distribution, including the mass distribution of unapproved and clinically untested compounded "semaglutide." While there are no verified estimates of how many patients are using compounded "semaglutide," some "industry officials" have recently estimated that the number of patients on compounded "semaglutide" could be in the millions. These compounders are compounding "semaglutide" without adhering to all the legal guardrails intended to ensure that compounding occurs only in appropriate circumstances and are engaging in these operations without the supply chain integrity and pharmacovigilance protections provided by sponsors of FDA-approved medications. We thus urge the Board to continue to bolster patient-centered policies at the state-level to protect patients from the risk of harm from compounded products. *See* Dani Blum, *More People Are Overdosing on Ozempic Alternatives*, NY TIMES (Aug. 6, 2024), https://www.nytimes.com/2024/08/06/well/ozempic-semaglutide-overdose-risks.html; *see also* Arthur Allen, *Why Millions Are Trying FDA-Authorized Alternatives to Big Pharma's Weight Loss Drugs*, KFF HEALTH NEWS (July 23, 2024), https://kffhealthnews.org/news/article/glp1-	Board staff thank the commenter for their comments, recognition of the Board's consumer protection mandate and acknowledges the patient safety concerns highlighted by the commenter. Board staff do not recommend any changes to the proposed text based on these comments.

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			compounding-pharmacies-wegovy-zepbound-copycat-drugs-shortages/.	
2	General	Kaiser Permanente	The commenter indicates that the Board has failed to provide empirical evidence to support the need for additional regulations that exceed USP compounding chapters. The commenter indicates that the Board has not considered the behaviors that its proposed regulations will incentivize and the second order effects that those practices will likely precipitate. Commenter believes that the problematic second order effects that these regulations will cause coupled with the lack of evidence to support the proposed regulations will have a net negative effect of California patients and California pharmacies. The commenter supports the following alternative: 1. The Board should repeal sections 1708.3. 1708.4, and 1708.5, 1735 et seq, 1751 et seq. 2. The Board should reject the proposed regulatory action. 3. The Board should enforce the provisions of the USP compounding chapters as required by California Business and Professions Code section 4126.8. If the Board elects to finalize the proposed regulations, the commenter encourages the Board to establish a rational effective date for these regulations that will provide the regulated public with ample time to come into compliance with these new requirements. The Board rejected our proposal because the USP compounding standards have been in effect since November 1, 2023, and because some of the provisions in the proposed regulations are in the Board's current compounding regulations. Both of those observations, which we do not dispute, are immaterial to the work that organizations will need to do to come into full compliance with the proposed regulations.	Board staff have reviewed the comments and do not recommend changes to the proposed text based on the comments received. Staff note that the Board have previously considered the comments, most recently during its January 8, 2025. The Board does not believe a delay in effective date is appropriate except were identified in the proposed regulation text. It has been common practice for the Board to focus on education of new requirements to facilitate compliance when immediate public harm is not at stake and where the licensee is making a good faith effort to come into compliance with new requirements.

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			Commenter states as written, Kaiser Permanente will need to make extensive updates to our policies and standard operating procedures, update our pharmacy information systems, and remodel some of our compounding facilities. These tasks are time-consuming, costly, or both. Commenter suggests at least one year from the date that the regulation is filed with the Secretary of State would be a reasonable effective date.	
3	General	CA Health Coalition Advocacy	CHCA opposes the regulations and expressed concern that the regulations supersede the FDA and exceed US Pharmacopeia standards and would restrict access to treatments that Californians find essential to their health. The commenter states that the proposed regulations would make Category 1 bulk substances, inaccessible through 503a pharmacies and therefore no longer available to patients in California. Finally, the commenter states that adoption of the regulations would cause harm to vulnerable patients, limit healthcare provider autonomy, and increase healthcare inequalities. The commenter indicates that Doctors should be able to prescribe treatments for their patients based on their expertise, research, and experience without interference from the Board of Pharmacy.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on the comments received. Board staff believe that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to bulk drug substances. Board staff believe the approach currently being proposed strikes an appropriate and necessary balance that both creates a pathway for pharmacies to legally compound using Category 1 bulk drug substances while ensuring that appropriate and feasible patient protection measures are in place. Provided below is the relevant language from both federal law and the USP with respect to bulk substances. The Board's proposed regulations provide a legal pathway to compound using bulk drug substances. As the Board has noted previously, until the FDA formally makes a determination regarding bulk drugs substances nominated for inclusion in 21 CFR 216.23, the Board has determined that there is a need at the state level to provide a pathway to allow for such compounding. **``SEC. 503A. PHARMACY COMPOUNDING**  ``(a) In General.--Sections 501(a)(2)(B), 502(f)(1), and 505 shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product

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				is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding-- ``(1) is by--  ``(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or ``(B) a licensed physician, on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or  ``(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and ``(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between--  ``(i) the licensed pharmacist or licensed physician; and ``(ii)(I) such individual patient for whom the prescription order will be provided; or  ``(II) the physician or other licensed practitioner who will write such prescription order. ``(b) Compounded Drug.--  ``(1) Licensed pharmacist and licensed physician.--A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician-- ``(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations--

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				``(i) that--  ``(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; ``(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or  ``(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d); ``(ii) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and  ``(iii) that are accompanied by valid certificates of analysis for each bulk drug substance; ``(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;  ``(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and ``(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

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				``(2) Definition.--For purposes of paragraph (1)(D), the term `essentially a copy of a commercially available drug product' does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product. ``(3) Drug product.--A drug product may be compounded under subsection (a) only if--  ``(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and ``(B) such drug product is compounded in a State--  ``(i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or ``(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician. [Page 111 STAT. 2330] The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(i).

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				``(c) Advertising and Promotion.--A drug may be compounded under subsection (a) only if the pharmacy, licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician. ``(d) Regulations.--  ``(1) In general.--The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections (b)(1)(A)(i)(III), (b)(1)(C), or (b)(3)(A), the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary. ``(2) Limiting compounding.--The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (b)(1)(A)(i)(III) for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify. ``(e) Application.--This section shall not apply to-- ``(1) compounded positron emission tomography drugs as defined in section 201(ii); or ``(2) radiopharmaceuticals.  ``(f) Definition.--As used in this section, the term `compounding' does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved

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				labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.". From USP: "When CSPs are used as components, see *16. Use of CSPs as Components*. All APIs and other components used must be evaluated for suitability for use in sterile drug preparation. Components labeled with "not for pharmaceutical use", "not for injectable use", "not for human use" or an equivalent statement must not be used to compound for these purposes. Further, from the FDA Guidance Document, Insanitary Conditions are Compounding Facilities (dated November 2020) which provides examples of insanitary conditions including " **Using active ingredients, inactive ingredients, or processing aides, that have or may have higher levels of impurities compared to compendial or pharmaceutical grade equivalents (e.g., ingredients with potentially harmful impurities, ingredients labeled with "not for pharmaceutical use" or an equivalent statement)** The Board's underlying data included in the Modified Initial Statement of Reasons contains additional information specifically related to this issue including as an example item 21, "FDA highlights concerns with using dietary ingredient glutathione to compound sterile injectables." Further, it appears that the commenter is suggesting that a pharmacist does not have an obligation to exercise clinical judgment when compounding or dispensing a medication. The Board believes it is important to underscore that pharmacists must exercise clinical judgment in all aspects of practice and not simple defer their judgment to another individual. This is obligation is memorialized throughout Pharmacy Law, including notably BPC Section 4306.5, Business and Professions Code Section 733, Health and Safety Code Section 11153 and California Code of Regulations Section 1707.3.

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4	General	Alliance for PHY Compounding	We continue to have serious concerns regarding the pathway outlined in the proposed regulations for compounding with active pharmaceutical ingredients (APIs) included in FDA's Interim Category 1. While the pathway appears to establish a mechanism for compounding, the associated testing and documentation requirements you propose create significant barriers that make compounding for all necessary dosage forms and strengths impractical under the revised proposed regulations. **1. Stability Studies**: o **USP Standards**: USP does not require full stability studies for sterile compounding under **Category 1 or 2**. Instead, USP aligns required tests with the beyond-use date (BUD) assigned to the compound. Full stability-indicating studies are only required for **Category 3**, which pertains to larger-scale compounding (typically batches of 250 units). o **California's Proposed Rules**: The requirement for full stability studies in all cases goes far beyond USP and FDA standards. Stability studies are expensive, costing **$10,000–$30,000 or more per formulation**. o **Impact on Pharmacies and Patients**: This requirement would force pharmacies to limit the formulations they produce, focusing only on the most common ones that justify the cost of stability studies. For example, a pharmacy might conduct a study for **glutathione 200 mg/mL multi-dose vials**, which serve the largest number of patients (IV, IM, and inhalation use, even though preservatives should not be inhaled). However, more specialized formulations, such as **an NAC/glutathione inhalation combination** or **preservative-free individual**	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on the comments received. Board staff believe that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to bulk drug substances. Staff note a recommendation was previously accepted to clarify the testing requirements in this section and the ability of the pharmacy to rely on testing performed by a manufacturer, repackager, or wholesaler. Board staff believe the approach currently being proposed strikes an appropriate and necessary balance that both creates a pathway for pharmacies to legally compound using Category 1 bulk drug substances while ensuring that appropriate and feasible patient protection measures are in place. Board staff note that under the provisions of the Chapter and the Board's proposed regulation text, a pharmacy **can use** the stability studies performed by another entity, including stability studies performed by professional organizations and associations. There is nothing in the regulation text requiring pharmacies to repeat these studies. Specifically related to the API comments, staff would recommend that a facility seeking to rely upon the tests performed either in full or in part to meet the requirements in 1736.17 should work with their supplier to provide the necessary information. Staff note that the proposed regulation text in this section does not require the testing results to be included on the COA, rather it needs to be available. As the Board has previously noted and the commenter suggests, USP provides, "Although it is possible for FDA or another government authority in the U.S. or elsewhere to require the use a USP General Chapter numbered 1000 to 1999, the authority in question would need to make this requirement expressly applicable under law, regulation, or another appropriate vehicle that prescribes enforceable requirements." The Board's proposed regulation text is consistent with this approach and the Board, in some instances, is explicitly adopting a Chapter.

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			inhalation vials, would become financially unviable. **2. API Testing Requirements:** o California proposes additional testing requirements for APIs that exceed what is required by USP or FDA. o These tests could be performed by the manufacturer, repackager, or wholesaler, but initial reviews suggest that these tests are not typically listed on Certificates of Analysis (COAs). This means pharmacies would likely need to perform the tests themselves, incurring additional costs and delays. **USP Chapters Above 1000** USP chapters numbered above 1000, such as **Chapter 1097** (which is referenced by the testing required for API in FDA's interim category 1), are intended for informational purposes and are not enforceable unless explicitly adopted. To illustrate the financial burden, a stability study quote of $40,000 for a commonly requested NAC/glutathione combination, used for its antioxidant effects to protect lung tissue from damage caused by free radicals and oxidative stress.	
5	General	Wedgewood	We also continue to advocate that the compounding standards should default to the clinical standards set by the United States Pharmacopeia in USP 795, 797, and 800 which have been adopted by most states with no additional requirements. We do not believe that reasonable clinical, or policy-based, justifications for exceeding these standards has been presented, which puts California residents' (both human and animal) access to safe and effective compounded medications prescribed by California-licensed providers at risk.	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Board staff respectfully recommend that the commenter review the rulemaking package in its entirety along with underlying data and referenced materials to gain a full understanding of the necessity for these proposed regulations.
6	General	CMA	CMA is disappointed by the Board's refusal to revise its proposed language to clarify that the regulations	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. The Board has

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			do not apply to physicians. In its response to public comment requesting clarification on whether the regulations apply to physicians and other licensed practitioners, the Board effectively stated the regulations do not apply to licensees of other healing arts boards, noting: "[…] [the] Board's regulations apply to licensees within the Board's jurisdiction. The Board's jurisdiction is limited to those businesses and individuals within its practice act." The language of the proposed regulations, however, is written in a manner that could be construed to apply to compounding in any setting and by any individual, because their scope is not expressly limited to pharmacists and pharmacies, unlike the current regulation.	considered this issue on several occasions most recently during its January 8, 2025, Board meeting. After consideration, the Board determined that the Board's regulations to not need to specify that the regulations do not apply to physicians and surgeons. As was previously shared, staff note the Board only has jurisdiction over individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a physician. Business and Professions Code section 4170(c) makes clear that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Profession Code) with respect to its licensees. It may be appropriate for the commenter to confer with their licensing board to discuss their concerns. Board staff note that the Medical Board of California has previously provided a written response to individuals inquiring about the applicability of the Board of Pharmacy's regulations to individuals and practices that operate under the jurisdiction of the Medical Board of California. Below is the information provided from the Medical Board - - Dear Ms. Sodergren: I understand that some concerns have been raised by stakeholders about the applicability of the Board of Pharmacy's pending compounding regulations to licensees of the Medical Board of California (MBC). Existing statute (see Business and Professions Code (BPC) section 2220.5) makes it clear that only the MBC can discipline its physician licensees. Whenever a physician is engaging in compounding (or any other action that their medical license authorizes them to perform) they must always do so consistent with the standard of care. For the purposes of MBC's enforcement program, the standard of care is established by expert testimony in the context of the facts and circumstances of a specific case. It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding, especially since some of the proposed regulations reflect what is already

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				required for physician compounding under federal law, including, but not limited to, Section 503A of the Federal Food, Drug, and Cosmetic Act (BPC section 2225(b) allows MBC to investigate violations of federal law related to the practice of medicine). Feel free to share this message with others as you see fit who might also be concerned about the applicability of their pending regulations to the physician community. Please contact me if you have any further questions. Sincerely, Reji Varghese Reji Varghese is the Executive Director for the Medical Board of California. The Medical Board is charged with evaluating compounding practices and the standard of care relevant to its licensees.
7	General	T. Tizon-Damiano, S. Guevara, P. Mirdamadi, M. O'Neil, M. Domyancic, K. Oleinik, E. Peterson, D. Valdez, C, Cohen	Commenters oppose the proposed regulations because they limit access to Category 1 sterile compounds.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on the comments received. Board staff believe that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to bulk drug substances. Board staff believe the approach in the second modified text strikes an appropriate and necessary balance that both creates a pathway for pharmacies to legally compound using Category 1 bulk drug substances while ensuring that appropriate and feasible patient protection measures are in place. Provided below is the relevant provisions from both federal law and the USP with respect to compounding with bulk substances. The Board's proposed regulations provide a legal pathway to compound using bulk drug substances. As the Board has noted previously, until the FDA formally makes a determination regarding bulk drugs substances nominated for inclusion in 21 CFR 216.23, the Board has determined that there is a need at the state level to provide a pathway to allow for such compounding. **``SEC. 503A. PHARMACY COMPOUNDING**

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				``(a) In General.--Sections 501(a)(2)(B), 502(f)(1), and 505 shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding-- ``(1) is by--  ``(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or ``(B) a licensed physician, on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or  ``(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and ``(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between--  ``(i) the licensed pharmacist or licensed physician; and ``(ii)(I) such individual patient for whom the prescription order will be provided; or  ``(II) the physician or other licensed practitioner who will write such prescription order. ``(b) Compounded Drug.--  ``(1) Licensed pharmacist and licensed physician.--A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician--

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				``(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations--  ``(i) that-- ``(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;  ``(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or ``(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d);  ``(ii) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and ``(iii) that are accompanied by valid certificates of analysis for each bulk drug substance;  ``(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; ``(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and

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				``(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.  ``(2) Definition.--For purposes of paragraph (1)(D), the term `essentially a copy of a commercially available drug product' does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product. ``(3) Drug product.--A drug product may be compounded under subsection (a) only if--  ``(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and ``(B) such drug product is compounded in a State--  ``(i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or ``(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician. [Page 111 STAT. 2330] The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of

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				understanding for use by the States in complying with subparagraph (B)(i). ``(c) Advertising and Promotion.--A drug may be compounded under subsection (a) only if the pharmacy, licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician. ``(d) Regulations.--  ``(1) In general.--The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections (b)(1)(A)(i)(III), (b)(1)(C), or (b)(3)(A), the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary. ``(2) Limiting compounding.--The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (b)(1)(A)(i)(III) for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify. ``(e) Application.--This section shall not apply to-- ``(1) compounded positron emission tomography drugs as defined in section 201(ii); or ``(2) radiopharmaceuticals.

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				``(f) Definition.--As used in this section, the term `compounding' does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.". From USP: "When CSPs are used as components, see *16. Use of CSPs as Components*. All APIs and other components used must be evaluated for suitability for use in sterile drug preparation. Components labeled with "not for pharmaceutical use", "not for injectable use", "not for human use" or an equivalent statement must not be used to compound for these purposes. Further, from the FDA Guidance Document, Insanitary Conditions are Compounding Facilities (dated November 2020) which provides examples of insanitary conditions including " Using active ingredients, inactive ingredients, or processing aides, that have or may have higher levels of impurities compared to compendial or pharmaceutical grade equivalents (e.g., ingredients with potentially harmful impurities, ingredients labeled with "not for pharmaceutical use" or an equivalent statement) The Board's underlying data included in the Modified Initial Statement of Reasons contains additional information specifically related to this issue including as an example item 21, "FDA highlights concerns with using dietary ingredient glutathione to compound sterile injectables."
8	General	M. Lindemann	The commenter opposes the proposed regulations for the following reasons: 1. Remove access to critical treatments. 2. Increase the financial burden on patients to access treatment. 3. Endanger patients by requiring patients to obtain the medication from underground sources.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on the comments received. Board staff believe that the commenter may, in part, be referring to proposed regulation sections 1736.9 and 1736.17 related to bulk drug substances. Board staff believe the approach in the second modified text strikes an appropriate and necessary balance that both creates a pathway for pharmacies to legally compound using Category 1 bulk

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				drug substances while ensuring that appropriate and feasible patient protection measures are in place. Provided below is the relevant provisions from both federal law and the USP with respect to compounding with bulk substances. The Board proposed regulations provide a legal pathway to compound using bulk drug substances. As the Board has noted previously, until the FDA formally makes a determination regarding bulk drugs substances nominated for inclusion in 21 CFR 216.23, the Board has determined that there is a need at the state level to provide a pathway to allow for such compounding. **``SEC. 503A. PHARMACY COMPOUNDING**  ``(a) In General.--Sections 501(a)(2)(B), 502(f)(1), and 505 shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding-- ``(1) is by--  ``(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or ``(B) a licensed physician, on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or  ``(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and ``(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of

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				the drug product, which orders have been generated solely within an established relationship between-- ``(i) the licensed pharmacist or licensed physician; and  ``(ii)(I) such individual patient for whom the prescription order will be provided; or ``(II) the physician or other licensed practitioner who will write such prescription order.  ``(b) Compounded Drug.-- ``(1) Licensed pharmacist and licensed physician.--A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician--  ``(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations-- ``(i) that--  ``(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; ``(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or  ``(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d); ``(ii) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

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				``(iii) that are accompanied by valid certificates of analysis for each bulk drug substance;  ``(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; ``(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and  ``(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product. ``(2) Definition.--For purposes of paragraph (1)(D), the term `essentially a copy of a commercially available drug product' does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product. ``(3) Drug product.--A drug product may be compounded under subsection (a) only if--  ``(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and ``(B) such drug product is compounded in a State--

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				``(i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or ``(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician. [Page 111 STAT. 2330] The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(i). ``(c) Advertising and Promotion.--A drug may be compounded under subsection (a) only if the pharmacy, licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician. ``(d) Regulations.--  ``(1) In general.--The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections (b)(1)(A)(i)(III), (b)(1)(C), or (b)(3)(A), the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary.

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				``(2) Limiting compounding.--The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (b)(1)(A)(i)(III) for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify. ``(e) Application.--This section shall not apply to-- ``(1) compounded positron emission tomography drugs as defined in section 201(ii); or ``(2) radiopharmaceuticals.  ``(f) Definition.--As used in this section, the term `compounding' does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.". From USP: "When CSPs are used as components, see *16. Use of CSPs as Components*. All APIs and other components used must be evaluated for suitability for use in sterile drug preparation. Components labeled with "not for pharmaceutical use", "not for injectable use", "not for human use" or an equivalent statement must not be used to compound for these purposes. Further, from the FDA Guidance Document, Insanitary Conditions are Compounding Facilities (dated November 2020) which provides examples of insanitary conditions including " Using active ingredients, inactive ingredients, or processing aides, that have or may have higher levels of impurities compared to compendial or pharmaceutical grade equivalents (e.g., ingredients with potentially harmful impurities, ingredients labeled with "not for pharmaceutical use" or an equivalent statement)

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				The Board's underlying data included in the Modified Initial Statement of Reasons contains additional information specifically related to this issue including as an example item 21, "FDA highlights concerns with using dietary ingredient glutathione to compound sterile injectables." Board staff note that the costs of medications are outside of the Board's purview; however, note that the Board has made a number of changes to the proposed regulation text where possible to address cost issues raised. Board staff note that under the law, patients can be dispensed medications from a variety of sources including physicians (and other practitioners authorized in the law), pharmacies, and outsourcing facilities. Patients may choose to explore other sources of compounded preparations.
9	General	W. Hicks Taylor And N. Holt	The commenter opposes the proposed regulation for the following reasons: 1. The Board is denying patient access to oral & IV Vitamin B12 and Glutathione. 2. The Board of Pharmacy has offered no scientific or legal justification for blocking access to Category 1 substances. 3. The Board has targeted the specialized pharmacies that compound & dispense Category 1 substances with these regulations and using taxpayer money to file lawsuits, claiming they were dispensing Category 1 substances improperly.	Board staff have reviewed the comment and do not recommend changes to the proposed text. Board staff respectfully refer the commenter to prior responses to this issue included throughout the rulemaking record and public discussion explaining that access is not being blocked; instead, a pathway is being allowed. Board staff would also recommend that the commenter review information regarding provisions in the Government Code to gain an understanding of the disciplinary process. The Board has received presentations from representatives from the Office of the Attorney General on the process during public meetings including during the July 18, 2023 Enforcement and Compounding Committee. The presentation slides are included in attachment 2 meeting materials available here and a livestream of the meeting is available on the Board's website and can be accessed from the following webpage - - https://www.pharmacy.ca.gov/about/meetings_enforcement.shtml. Further the Board notes that it is a special fund agency that does not rely on general taxpayer funding.
10	General	M. Morgenstern	As a Lyme Patient that has found B12 & Glutathione injections imperative and beyond helpful in my treatment I am horrified that you are ignoring an abundance of intelligent public comments from	Board staff have reviewed the comment and do not recommend any changes to the text. Board staff respectfully refer commenter to prior responses to this issue included throughout the rulemaking

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			MDs, Naturopaths, Veterinarians, and Pharmacists along with Firefighters regarding your proposed new restrictions on compounded supplements. Your desire to tighten restrictions on compounded medications is senseless and overreaching. The current regulations are already enough to keep patients safe. Our firefighters that have been working diligently to save lives and homes in California deserve your support instead of your overly controlling restrictions. Please do not make it more difficult and more costly for our firefighters, immune compromised patients and pets to detox utilizing glutathione and other supplements. Your reasons for wanting to tighten restrictions are transparent and lack integrity. Medical Doctors do not need anymore needless restrictions from the board regarding how they choose to treat and help patients. Same with Pharmacists. As a California Councilmember I am appalled at the fact that you are not listening to public comments. Listen to the people of California! Do better!!! I know I am not the only person in Sonoma County California that is appalled with your inability to listen to the public. The board is pretending they know best and that medical doctors and pharmacists do not. Come back down to earth and start listening to the residents and voters of California. Some of the condescending comments the board makes are offensive.	record and public discussion regarding providing a pathway for the appropriate and legal use of bulk substances in compounding.
11	General	C. Frost	These regulations, as currently written, will devastate patient access to life-saving treatments in California, despite no evidence of safety risks warranting such measures. **USP does not require full stability studies for Category 1 or 2 sterile compounding.** These requirements only apply to Category 3 compounding. For the Board to mandate such studies—which can cost $10,000 to	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text. Board staff respectfully refer the commenter to the public record of this rulemaking including responses provided related to the commenter's statements related to stability studies, documentation for clinical necessity and provisions related to incorporation of USP Chapters above 1000.

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			$30,000 per formulation—imposes an insurmountable financial burden on pharmacies. This will force them to limit offerings to the most generic formulations, eliminating the ability to create customized treatments based on individual prescriber orders. ● The **additional documentation of clinical circumstances** for APIs on the FDA's interim Category 1 list far exceeds FDA requirements. These APIs are already treated like any other active ingredient under FDA guidelines, with no such documentation mandate. ● The requirement to perform multiple tests on APIs, including **tests listed in USP Chapters above 1000** (informational-only chapters), is both excessive and unprecedented. California would be the only state enforcing such standards on 503As, further restricting access without improving safety. As a regulatory body, **your job is to listen to public comments and adjust your actions accordingly**. Under no circumstances is it appropriate to hold it against the public that the Board's hard work went into a proposal when said proposal ultimately harms the public interest. This Board has a moral and ethical obligation to protect the public. Instead of actively making it harder for Californians to access critical treatments, preserve access by fixing this proposal. **Our asks are simple:** 1. Align California's regulations with federal standards to ensure patients have access to essential Category 1 sterile compounded medications. 2. Adhere to USP by allowing Category 2 compounding without requiring full stability studies, provided sterility and endotoxin testing is performed and a reasonable beyond-use-date (e.g., 45 days refrigerated) is applied.	Board staff note that under the provisions of the Chapter and the Board's proposed regulation text, a pharmacy **can use** the stability studies performed by another entity, including stability studies performed by professional organizations and associations. There is nothing in the regulation text requiring pharmacies to repeat these studies. Staff note APIs included in the FDA's Interim Bulk Substances Guidance document are not treated exactly like other active ingredients. The Board is adhering to the rulemaking process and the Board's consumer protection mandate. Specifically related to the four specific requests the Board provides the following responses. 1. The Board's regulations align with federal standards and help licensees navigate the federal law and national standards that would otherwise prohibit compounding of substances such as glutathione. 2. The Board's requirements for stability studies align with the USP Chapters with one deviation specifically related to the use of Category 1 substances. As articulated elsewhere in the public rulemaking file, this deviation is necessary to ensure the stability of a compounding preparation that uses a chemical that is not approved by the FDA. 3. As stated elsewhere in the public rulemaking document, As the Board has previously noted and the commenter suggests, USP provides, "Although it is possible for FDA or another government authority in the U.S. or elsewhere to require the use a USP General Chapter numbered 1000 to 1999, the authority in question would need to make this requirement expressly applicable under law, regulation, or another appropriate vehicle that prescribes enforceable requirements." 4. Board staff respectfully refer the commenter to row 6 of this document for its response to this item. The Board has stated clearly that its authority is regulating licensees within its jurisdiction. The Board has provided

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			3. Eliminate adherence to USP Chapters above 1000, which are not enforceable requirements and are meant for informational purposes only. 4. Amend the language to specify that Title 16 sterile compounding regulations apply specifically to pharmacists and not to doctors. The Board's mission should be to protect public health—not restrict access to therapies that enhance patient outcomes.	information from the Medical Board, who is vested with the authority to regulate physicians specifically related to this issue.
12	General	S. Johnson	The proposed regulations exceed the Board's statutory authority, as they impose restrictions that are not supported by substantiated evidence or scientific justification. The Board has failed to substantiate the regulatory basis for these actions, which contravenes the requirement for evidence-based decision-making in rulemaking processes. These restrictions contradict federal guidelines for legally permitted FDA Category 1 substances, and the Board has provided no scientific justification, constituting an overreach of regulatory authority. A biased, inaccurate "education" presentation at the November meeting further reflects the Board's lack of transparency. These regulations exceed FDA standards without demonstrating added safety benefits, as outlined in the Initial Statement of Reasons (ISOR). They would disrupt pioneering research by institutions such as Stanford, UCSF, Scripps, and the Open Medicine Foundation, global leaders in Long Covid and ME/CFS studies. By denying access to FDA Category 1 substances in sterile compounds, the California Board of Pharmacy will directly contribute to the worsening health crisis facing our state. The Board's actions will not only undermine public health but will increase suffering for millions of Californians who need these	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that these comments mirror the comments previously considered by the Board including most recently at the January 8, 2025, board meeting. Staff respectfully refers the commenter to the Board's prior response. Board staff note that nothing in the Board's regulations would disrupt research being conducted. During the January 8, 2025, Board Meeting, information was provided about the opportunity for research through the California Firefighter Cancer Prevention and Research Program through the University of California. The proposed regulations do not disrupt research efforts. . The FDA has information available about how to conduct clinical drug trials. Board staff respectfully suggest that a source to learn more about clinical trials for drugs can be found on the FDA website. As is indicated in prior responses, the Board's regulations do not ban access to FDA Category I substances. Board staff note that under the provisions of the Chapter and the Board's proposed regulation text, a pharmacy **can use** the stability studies performed by another entity, including stability studies performed by professional organizations and associations. There is nothing in the regulation text requiring pharmacies to repeat these studies.

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			treatments to manage their health in the aftermath of an ongoing environmental disaster. New stability testing requirements will create undue financial hardship on pharmacies and patients, making life-saving medications less affordable and accessible. The Board has ignored the overwhelming public opposition and expert testimony, failing to address concerns from healthcare professionals and patients. The failure to accommodate patients with disabilities by restricting access to compounded medications and restricting their meaningful engagement as key stakeholders throughout the public rulemaking process violates their rights under the Americans with Disabilities Act (ADA). See comment for provided reference material.	Board staff have considered the references provided by the commenter. The references include videos and articles and other websites providing information related to environment hazards and long-term consequences including respiratory health. Based on staff review these references do not appear to be related to compounded preparations but appear to document, for example, how to improve air quality, steps to improve environmental quality, etc. Reference was also provided to the DQSA, which the Board also references in its public rulemaking file.
13	General	W. Hamik	Commenter shares deep concern and strong opposition to the proposed regulations that would severely restrict access to Category 1 sterile compounds like glutathione (GSH) and methylcobalamin (methyl B12). I feel compelled to voice how detrimental this overreach could be to the health and well-being of countless Californians. • Compounded medications like glutathione and methylcobalamin are indispensable for managing chronic illnesses such as long COVID, Lyme Disease, and ME/CFS. These conditions are complex and debilitating, often leaving patients without effective conventional treatments. • These compounds are also crucial for detoxifying individuals exposed to hazardous chemicals. • There are no true alternatives to these compounded medications. Over-the-counter supplements simply do not offer the potency or bioavailability that compounded IV infusions or	Board staff have reviewed the comment and do not recommend changes to the proposed text. Board staff respectfully refer the commenter to the public record of this rulemaking including responses provided above in this document related to the chemicals listed in the comment.

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			subcutaneous injections provide. Without access to these therapies, many patients will face worsening health crises and deteriorating quality of life. Restricting access to these compounds would disproportionately harm those with complex medical needs who have no other viable treatments. By moving forward with these restrictive regulations, the state risks abandoning this legacy and falling behind the rest of the nation in providing patient-centered care. Reconsider the broader implications of these regulations and prioritize the needs of Californians who depend on access to these life-changing treatments.	