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General	Dan Baxter CA Veterinary Medical Assoc	CVMA requests that a specific statement be included in this proposed regulatory revision to affirmatively state that it does not apply to veterinarians who compound medications for patients in their practices. California Business and Professions Code section 4826.5 provides statutory authority for veterinarians to compound medications in practice pursuant to regulations promulgated by the Veterinary Medical Board. California Code of Regulations, Title 16, Article 11 in turn specifies requirements for veterinarians to perform compounding in practice. The CVMA has received multiple inquiries from confused veterinarians regarding which regulations apply to them. A clear statement from the Board of Pharmacy that its proposed regulations do not apply to veterinarians would alleviate that unnecessary confusion.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on this comment. Staff note the Board only has jurisdiction over individuals and businesses within its practice act. Board staff read the comment as suggesting it is unclear whether the Board's proposed regulations would apply to a veterinarian. Business and Professions Code section 4170(c) makes clear that the Veterinary Medical Board is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Professions Code) with respect to its licensees. **Note**: Business and Professions section 4111 generally establishes prohibitions on individuals that can own a pharmacy. Specifically, 4111(a)(1) prohibits a person or persons authorized to prescribe or write a prescription from owning a pharmacy. It may be appropriate for the commenter to confer with the Veterinary Medical Board (VMB) to understand the requirements for veterinarian compounding under VMB authority.
General	CA Medical Association	We request that the Board revise the proposed compounding regulations to clarify that the regulations do not apply to compounding by licensed physicians, consistent with the Board's intended effect. While the Board does not have jurisdiction or disciplining authority over physicians and surgeons, the Medical Board may discipline a physician and surgeon for violating any provision of the Medical Practice Act or any other provision of Division 2 of the Business and Professions Code. It is certainly	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment. 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 that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Professions Code) with respect to its licensees. **Note**: Business and Professions section 4111 generally establishes prohibitions on individuals that can own a pharmacy. Specifically, 4111(a)(1) prohibits a person or persons authorized to prescribe or write a prescription from owning a pharmacy.

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		possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding, especially since some of the proposed regulations reflect what is already required for physician compounding under federal law, including, but not limited to, Section 503A of the Federal Food, Drug, and Cosmetic Act (BPC section 2225(b) allows MBC to investigate violations of federal law related to the practice of medicine)	It may be appropriate for the commenter to confer with their licensing board to determine if the scenario described their comment is allowable within their practice. 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 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 Business and Professions Code section 4001.1 provides that protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the

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			protection of the public shall be paramount. The Board believes the proposed regulations are consistent with its statutory mandate.
General	Stanford Health Care	While we appreciate the Board's rationale outlined in the Initial Statement of Reasons document for the proposed changes, we do not share the sentiment that additional requirements are necessary to "strengthen" United States Pharmacopeia (USP) chapters <795>, <797>, or <800> standards. We strongly urge the Board to adopt USP chapters <795>, <797>, and <800> as currently written. We acknowledge that in the past, additional requirements for compounded drug products from the Board were necessary due to outdated USP standards; however, this is no longer a concern. The published revisions of USP <795>, <797>, and <800> have undergone extensive review and careful decision-making by an expert committee. Revised chapters are now both current and comprehensive. Furthermore, creating new requirements that do not align with other regulatory and accreditation bodies (e.g., California Department of Public Health, The Joint Commission) can lead to confusion and unnecessary challenges in maintaining compliance.	The Board thanks the commenter for their consideration and understanding of the Board's policy goals and consumer protection mandate. The Board notes that federal law and the USP Compounding Chapters serve as an important foundation. The Board has current regulations governing compounding, hazardous drugs, and radiopharmaceuticals. The Board's approach to regulation in this complex area of practice must remain for patient safety. The Board has determined that Board regulations generally will not restate federal law and USP Chapters but will clarify and make more specific requirements, consistent with this authority. The Board notes that USP Chapters, while comprehensive, are many times not written in an enforceable manner and, further, do not address all patient safety issues. As examples, USP throughout Chapters, defers to regulators for requirements. In addition, nothing in USP or federal law establishes requirements for notification to the Board for example of an adverse drug experience (ADE). As the primary regulator of sterile compounding pharmacies, it is vital for the Board to specify all necessary protections to ensure both the Board and the regulated public have a clear and comprehensive understanding of the requirements for compounding. The Board's proposed regulations therefore provide additional requirements and definitions to promote public protection. The Board relied on a variety of sources of information in developing its regulations, including information from the FDA, USP, ASHP, enforcement actions to name a few. The Board notes that its approach is similar to the approach taken in some other states as well as the National Association of Boards of Pharmacy (which perform inspections of compounding pharmacies for accreditation purposes.) Board regulations may go above what is required by other agencies in some instances; however, staff are not aware of any of its regulations that are in conflict with accreditation standards.
General	CA Hospital Association	CHA does not believe the proposed modifications will enhance protection or promote health and safety. Additionally, they are duplicative of federal law.	Board staff have reviewed the comment and do not recommend changes to the proposed text based on comments received. Board staff respectfully disagree with the view that the proposed modifications will not enhance protection or promote health and safety. The Board has provided significant information through its

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		CHA believes that when states implement their own regulations on areas already covered by federal law, it leads to regulatory redundancy, which burdens businesses, individuals, and government agencies with unnecessary compliance efforts, legal complexities, and costs. CHA believes that the Board has not produced empirical evidence indicating either systemic challenges or that patients have been placed in harm's way — or that hospital pharmacies are not meeting safety standards that might necessitate additional regulations. Regulations lacking a solid evidence base will lead to unnecessary compliance costs for hospitals, and they may lead to confusion and legal disputes between regulators and businesses.	rulemaking documents, public discussion, and presentations that supports the need for the regulations and has engaged in a collaborative process with the development of the proposed regulations. Further, through the formal rulemaking process the Board has thoughtfully considered comments received and, in response to comments, made additional changes to the proposed text. Board staff note that the Board's Enforcement and Compounding Committee receives annual presentations on inspection findings, citations issued and enforcement actions taken for all pharmacies, including hospitals. This information is available on the Board's website.
General	CSHP	CSHP believes that the business and economic impact identified in the ISOR is a gross underestimation of the associated costs. The Board should actively seek input from experts who can inform the Board as it relates to both the Business and Economic Impact. CHA requests the regulations be suspended so the Board can re-evaluate the Business and Economic Impact and to provide evidence the current regulations fail to address patient safety outcomes.	Board staff have reviewed the comments and do not recommend any changes to the proposed text based on the comments. Board staff note that the proposed regulations have been developed over the course of several years, providing many opportunities for engagement with interested stakeholders. Board staff note that the changes in USP Chapter standards resulted in additional costs to facilities. The Board has amended some of the language of the proposed text to address costs in response to the 45-day comment period. Staff respectfully disagree with the assertion that the Board has not engaged with experts. Staff note that two members of the Board are experts in compounding and system implementation. Further, the Board has experts on staff that have been extensively involved in the development of the regulations. Board staff complete significant training in compounding including receiving trainings from experts in a variety of areas including experts in USP 825, USP 797 room certification, etc. Board staff routinely complete USP and FDA training and participate in national meetings on the topic.

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			Board staff also attended all of the USP Compounding meetings before the USP released its final standards. In addition, the Board seeks expert advice through a variety of other means including consulting with experts with a variety of different backgrounds including laboratory experts, veterinary practice, radiopharmaceutical practice, certification of rooms and equipment, other state regulators and accrediting agencies. The Board also collaborates with the FDA.
General	FlavoRx	Commenter provided a comprehensive listing of every mention of medication flavoring at the state level, either in statute, rule, or guidance.	Board staff have reviewed the information provided and appreciate the information provided. While the commenter did not provide specific provisions of the proposed regulation text for suggested change, other commenters did. With the provisions identified by the other commenters, Board staff are recommending changes to the proposed text. Board staff recommend the addition of a subdivision specifically related to flavoring agents and an addition to 1735.1(i) and Section 1735.15 related to compounding by combining a flavoring agent with an FDA approved drug in an oral liquid solution.
General	React 19	**Why These Regulations Harm Patients:** **Unnecessary Barriers to Critical Treatments -** The proposed regulations impose restrictions that go beyond federal FDA guidelines. Implementing regulations that conflict with and exceed FDA guidelines creates unnecessary barriers to care for patients and burdens for providers. **Disproportionate Impact on Vulnerable Populations -** By restricting access, the Board risks leaving these individuals without any viable options, forcing them to endure worsened symptoms and diminished independence. **Risks to Medical Innovation -** Sterile compounded medications are indispensable for advancing research into neglected conditions like Long Vax.	Board staff have reviewed the comments and do not recommend any changes to the proposed text based on the comments. Board staff note that development of the proposed regulations have occurred over the course of several years, providing many opportunities for engagement with interested stakeholders. Staff note that two members of the Board are experts in compounding and system implementation. Further, the Board has experts on staff that have been extensively involved in the development of the regulations. Board staff complete significant training in compounding including receiving training from experts in a variety of areas including experts in USP 825, USP 797 room certification, etc. Board staff routinely complete USP and FDA training and participate in national meetings on the topic. Board staff also attended all of the USP Compounding meetings before the USP released its final standards. In addition, the Board seeks expert advice through a variety of other means including consulting with experts with a variety of different backgrounds including laboratory experts, veterinary practice, radiopharmaceutical practice, certification of rooms and equipment, other state regulators and accrediting agencies. The Board also collaborates with the FDA.

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		Undue Influence - These restrictions not only disregard the needs of patients but also raise concerns about the motivations driving them, suggesting undue influence by pharmaceutical interests over patient care. **What's at Stake -** The Board risks sending the message that their suffering is invisible and their lives expendable. **Recommendations** React19 urges the Board to: 1. Withdraw the Proposed Regulations and align policies with evidence-based federal standards under FDA sections 503A and 503B. 2. Engage Stakeholders—including patients, clinicians, and researchers—in developing patient-centered guidelines that reflect real-world needs. 3. Delay Implementation to assess the regulations' unintended consequences on patient care and research.	
General	Crystal Frost	Commenter believes that the proposed regulations threaten to dismantle the fragile lifeline that many patients, caregivers, and healthcare providers depend on. Your decision to advance these regulations, which severely restrict access to Category 1 sterile compounded treatments, is not just a regulatory overreach—it is a decision with profound and unjustified human consequences. **Impact on Patient Access: A Matter of Life and Death** These compounded treatments are not a luxury or a choice for the patients who rely on them. They	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 1736.9 and 1736.17 related to bulk drug substances. Staff note a recommendation is being offered 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. Please refer to the sterile compounding responses for additional information. 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.

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		are a necessity. They represent the only effective medical interventions for individuals whose conditions cannot be addressed by standard pharmaceuticals. **Arbitrary and Unjustifiable Regulations** The proposed amendments exceed federal and U.S. Pharmacopeia (USP) standards in dozens of ways, going far beyond what is required to ensure patient safety. They introduce barriers that are unnecessary and unsupported by evidence. **Redundant Stability Testing: An Unnecessary and Costly Barrier Rooted in Misinformation** The proposed amendments introduce stringent stability testing requirements for compounded medications, imposing significant financial burdens on compounding pharmacies. These costs will inevitably be passed on to patients, many of whom are already struggling to afford these essential treatments. Custom medications from compounding pharmacies are often the only option for patients with unique health needs, and the added expense from redundant testing threatens to make these treatments inaccessible. Imposing redundant testing requirements appears to be less about addressing real gaps and more about creating excessive financial and logistical barriers for compounding pharmacies,	Provided below is the specific language of federal law and the USP that the Board is seeking to add clarity through its regulations to 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 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

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		effectively pricing out vulnerable patients and eliminating access to life-saving treatments. This approach is not only unjustified but harmful. Commenter believes that the Board is "fearmongering" and "misrepresenting" federal laws. Additionally, commenter states that the Board is enforcing underground regulations. Board has cited these underground regulations in a claim that certain compounded substances lack USP drug monographs or are not of "pharmaceutical grade." However, this reasoning is fundamentally flawed. The FDA does not define or regulate "pharmaceutical grade" as a standard for compounding substances. Instead, the FDA evaluates compounded medications based on whether they are prepared using components that comply with existing USP standards or are listed on the 503A Bulks List. The Board's reliance on non-existent terminology and unsubstantiated assertions demonstrates a lack of understanding of federal guidelines and creates unnecessary confusion for pharmacies and patients alike. Commenter states that the Board is ignoring federal law by restricting 503A Bulks list substances.	``(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  ``(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

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			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--  ``(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.  ``(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.''.

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			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. The Board's underlying data includes additional information specifically related to this issue. Board staff note that the commenter has provided information about medical claims for the use of some of these bulk drug substances. It is recommended that the commenter reach out of the FDA, which is the regulatory agency responsible for reviewing and determining which bulk drug substances are appropriate for inclusion in the federal regulations as well as the determining the appropriate clinical use of such bulk drug substances.
General	54 Commenters	These commenters oppose the restriction of compounded medication, including B12, Glutathione.	Board staff have reviewed the comment and do not recommend changes to the proposed text based on the comments provided. Board staff note that the Board's regulations establish provisions for compounding using bulk drug substances that are NOT included as part of the federal regulations under 21 CFR216.23 and provide a path to meeting the component requirements established in the USP. As included in the proposed responses to comments received related to sterile compounding requirements described in other responses, staff are recommending clarification related to the proposed testing requirements.
General	47 Commenters	These commenters oppose the restriction of compounded medication. Additionally, the commenters indicate that: • There was an unexpected presentation at the November Board meeting that contained inaccurate and misleading information. • There has been no cooperation with pharmacies, hospitals, providers, or patients.	Board staff have reviewed the comments and do not recommend any changes to the proposed text based on these comments. The comments are general in nature. Staff provide the following general responses. 1. The Board's November 6-7, 2024, Board meeting agenda appropriately noticed the presentations. 2. The Board has provided multiple opportunities for stakeholders to engage in the development of the proposed text. Further the rulemaking process has so far provided two formal comment periods in addition to a regulation hearing. 3. The Board notes that many of the costs identified are not related to the cost of the Board's regulations but the costs to

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		• Would put an unreasonable financial burden on hospitals and other providers. Commenters request that the Board adopt the USP standards.	comply with the national standards established in the USP. A recommendation to further modify the proposed text is being offered specifically related to the testing of bulk drugs substances. (Refer to the comments in response to comments received related to sterile compounding requirements.) The Board has modified the text through the rulemaking process to address concerns related to costs, including the requirements for use of disposable preparation mats, provisions for changing gloves, etc. Further additional proposed changes are being offered in this area. Compliance with the USP standards is established in federal and state law.
General	27 Commenters	These commenters oppose the restriction of Category 1 sterile compounds. Additionally, commenters indicate that the Board has not provided empirical evidence to justify the restrictions, has not engaged with stakeholders, and denied ADA accommodations. Commenters request exemption for medications with no FDA approved alternatives and request a one year delay in implementation.	Board staff have reviewed the general comments and do not recommend changes based solely on these comments. Staff have recommended changes based on specific comments received related to the use of Category 1 bulk drug substances. These recommendations are reflected in the responses to specific comments in the related regulation sections. Board staff respectfully disagree with the assertion that the Board has not engaged with stakeholders and direct the commenters to the Initial Statement of Reasons, which provides information on the public meetings convened in the development of the proposed regulations. The Board further respectfully disagrees with the assertion that the Board has improperly denied ADA accommodations. When accommodation requests are received, the Board works with legal counsel and adheres to applicable provisions of the law in evaluating and responding to the request. The Board has considered delayed implementation and identified specific areas that are appropriate for additional time to comply. In such instances the proposed regulation text reflects additional time to comply.
General	Chance Dite	The commenter expressed concern about the possible hindrance to effective care to treatments that are not available through standard channels. The commenter states false information was provided by individuals without medical expertise. The commenter request that the Board	Board staff have reviewed the comment and do not recommend changes to the proposed text based on these general comments. Staff are recommending changes to the proposed text related to bulk drug substances to clarify that the SOP provisions in 1736.17 to more explicitly state that the testing does not need to be done by the pharmacy. Further, Board staff note that the stability testing requirements established in the Chapter establish provisions to allow for the use of

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		adopt the USP standards and allow Category 1 substances.	stability studies conducted by other entities under specified conditions. There is nothing in the Board's proposed regulation text that change that flexibility.
General	Bobgo1970@gmail.com	The standard to which the Board attempts to hold pharmacies accountable is based on their usage of a term - 'pharmaceutical grade' - which has no specified legal or official definition within the FDA's regulations. 'Pharmaceutical grade' is indeed a commonly utilized term, despite the fact that it lacks a concise definition. USP797, which deals exclusively with compounding of Sterile products, in section 9.3.1, states an API "Must comply with the criteria in the USP–NF monograph, if one exists", thus implying that an API MAY be used even if a USP-NF monograph does not exist. Commenter urges the Board to allow sterile compounding of substances that do not have USP drug monographs but are listed in the 503a category 1 bulk drug substances list and that do meet quality requirements for sterile compounding. Commenter requests clarification on the applicability of the regulations to Physicians, Veterinarians, and 503b substances. Remove need for category 3 CSP standards for compounding of category 1 bulk substances to preserve access for patients, as this is NOT an FDA requirement and we have not seen scientific validation for this requirement. Also remove need for these substances to be available	Board staff have reviewed these general comments. Board staff do not recommend any proposed changes to the text based on these general comments but note that Board staff are recommending changes based on the specific comments received. Board staff note that the commenter only provides a portion of section 9.3.1. Chapter 797 includes additional language that must also be read to understand the full requirements of the Chapter. Staff also note that federal law establishes provisions related to the types of substances that can be used in compounding, including provisions for the use of bulk drug substances. The Board's proposed regulations establish provisions for compounding using specified bulk drug substances under specified conditions and staff are recommending addition changes to the proposed modified text in CCR Section 1736.17 related to SOP requirements. The Board appreciates the commenter referencing the applicability of USP Chapter 232. The Board agrees with the applicability of this USP Chapter and references USP Chapter 232 in the proposed text related to SOPs in proposed section 1736.17. Below are responses to the specific summary issues. 1. The commenter requests that the Board explicitly add to the new regulations language that would allow sterile compounding of substances that do not have USP drug monographs but are listed in the 503a Category 1 bulk drug substances list and that do not meet quality requirements for sterile compounding. Board staff note that the proposed modified text released for the 30-day comment period include such provisions. (Refer to proposed regulations 1736.9(e)(1) and 1736.17(a)(2)(E) 2. The Board note that 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. 3. The commenter requests that the Board discuss requirements for outsourcing facilities. Board staff note that outsourcing facilities must comply with current good manufacturing practices (cGMP) and separate Board regulations. The

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		only via 503a patient specific pharmacies, if these regulations ARE intended to apply to outsourcing facilities as well. Commenter summarizes with five summary issues. 1. Explicitly allow the sterile compounding of substances that do not have a USP pharmaceutical monograph but that appear on the category 1 Bulks list, if sterile compounding of such substances is not prohibited by the FDA bulks list document, and as long as they meet commonly accepted standards for pharmaceutical grade including impurity testing, regardless of whether a USP pharmaceutical monograph exists for that substance. 2. Revisions to explicitly limit your compounding regulations to pharmacists, not to in-office compounding by nurses, physicians, veterinarians, dentists, and naturopaths, as allowed in USP797, to prevent the CA BOP from targeting other professionals as practicing pharmacy without a license or attempting to regulate their compounding practices. 3. Include both 503a AND 503b bulk category 1 substances as those allowed to be compounded (as consistent	proposed regulations in sections 1735 et seq, 1736 et. seq, 1737 et seq, and 1738 et seq do not apply to outsourcing facilities. 4. The commenter suggests that the Board's proposed regulation text requires compliance with all requirements for Category 3 USP standards if compounding with Category 1 bulk drug substances. Board staff believe this comment is referring to requirements in proposed section CCR 1736.9(e)(2)(A)(i). The proposed regulation text in this area only require compliance with USP Chapter 797 stability testing, not all provisions related to Category 3 compounding. As indicated elsewhere in the Board's proposed responses to comments received, the USP Chapter establishes provisions to allow for an individual or entity to rely on the stability testing conducted by another entity under specified conditions.

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		with current FDA regulations), or explicitly state that the regulations are not intended to regulate outsourcing facilities so that their ability to compound 503b bulks substances is not impacted. 4. Remove need for category 3 CSP standards for compounding of category 1 bulk substances to preserve access for patients, as this is NOT an FDA requirement and we have not seen scientific validation for this requirement. Also remove need for these substances to be available only via 503a patient specific pharmacies, if these regulations ARE intended to apply to outsourcing facilities as well. The commenter also submitted a specific comment related to 1736.1(b)(1). Response to this comment is provided in the response to comments related to sterile compounding.	
5. General	Julip Thomas	Commenter expressed concern about the regulations: **No Evidence to Justify Restrictions**: The Board hasn't provided any solid evidence that these changes are needed or that they'll prevent harm. **Procedural Issues**: Disabled stakeholders were denied ADA accommodations and forced to wait for hours to comment, worsening their health in the process.	Board staff have reviewed the comments and do not recommend any proposed changes in response to these general comments, but note that Board staff are recommending changes based on the specific comments received, included proposed changes to section 1736.17 related to SOPs for compounding with the bulk drug substances referenced in the comments from this commenter. The Board has considered delayed implementation and identified specific areas that are appropriate for additional time to comply. In such instances the proposed regulation text reflects the additional time to comply.

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		Harm to Patients: These rules would block access to life-saving therapies for people with conditions like Long COVID and ME/CFS, who rely on compounded medications because there are no FDA-approved options. **Unanimous Public Opposition**: Every comment submitted has been against these rules, but the Board continues to push them forward without addressing the concerns raised. **Favoring Big Pharma**: It seems that the regulations would benefit pharmaceutical companies, particularly in the case of GLP-1 therapies, while restricting access to compounded treatments that many patients depend on. At a minimum, I respectfully ask the Board to consider exemptions for Essential Compounded Medications: Please allow exemptions for critical compounded treatments like glutathione, NAD+, and vitamin B12 for patients who have no FDA-approved alternatives. One-Year Delay: A one-year delay would give stakeholders more time to adapt and allow for better consultation to make sure the final decision is well-informed and doesn't disrupt patient care	
General	Sara Johnson	Commenter opposes the regulation for the following reasons: **Denial of Requested Accommodations**:	Board staff have reviewed the general comments and do not recommend any changes to the proposed regulation text based on these general comments but note that staff are recommending a number of changes based on specific comments received, which may also address some of the issues suggested by the commenter.

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		Commenter requested accommodations to make a comment early for an agenda item because the hours-long wait would exacerbate a disability. The request was supported by detailed medical documentation; however, the accommodation was denied, and no alternative solutions were offered. **Lack of Transparent Stakeholder Engagement:** Commenter states that the Board has not provided evidence of meaningful engagement with key stakeholder groups that the proposed regulations would directly impact. **Violation of the Board's Mission** Commenter states the proposed regulations directly contradict this mission by restricting access to therapies essential for vulnerable patients and critical research efforts. **Harm to Vulnerable Patients** Commenter states the proposed regulations fail to account for the real-world consequences of restricting sterile compounded medications for vulnerable populations. Patients with complex chronic illnesses like ME/CFS and Long COVID rely on compounded therapies as lifelines. **Lack of Supporting Evidence in the ISOR** Commenter states the Initial Statement of Reasons lacks empirical evidence demonstrating risks posed by current compounding practices and	Denial of Requested Accommodation: Board staff respectfully disagree that the Board has improperly denied ADA accommodations. When an accommodation request is received, the Board works with legal counsel and adheres to applicable provisions of law in evaluating and responding to the request. Board staff further note that the commenter has been provided with the process to file a formal complaint consistent with DCA policy. Lack of Transparent Stakeholder Engagement: Board staff respectfully disagree. Staff refer commenter to the public rulemaking record that documents the development of the proposed regulations and opportunities for participation by interested stakeholders. Violation of the Board's Mission. Board staff respectfully disagree. Harm to Vulnerable Patients. Board staff believe the commenter may be referring specifically to provisions related to compounding with bulk drug substances. Board staff note recommendations are being made to further amend the proposed text in CCR 1736.17 related to compounding with bulk drug substances. Lack of Supporting Evidence in the ISOR: Board staff have reviewed the comment and respectfully disagree. The Initial Statement of Reasons, public records, as well as information released from the FDA including its evaluation on the safety of a number of bulk drug substances has been considered and is available for the public to review. Where the public believes that a bulk drug substance is appropriate for inclusion in the federal regulation 21 CFR 213.23, individuals should consider following the FDA process for recommending such. Until such time as such bulk drug substances are formally approved by the FDA for use in compounding and included in the federal law, pharmacies can follow the Board's proposed regulations to use specified substances in compounded preparations. Absence of Evidence of Harm: Board staff have reviewed the comment and respectfully disagree. Board investigations and public documents from the Board, the FDA, ISMP, the Pew Charitable Trust and others have identified harm stemming from compounding practices.

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		overlooks the well-established safety records of therapies like glutathione, NAD+, and vitamin B12. **Absence of Evidence of Harm** Commenter states the ISOR does not present data showing harm from existing compounding practices in California. While there have been isolated incidents in other states—such as the 2012 New England Compounding Center (NECC) tragedy in Massachusetts—these events are not reflective of practices in California. **Double Standards in Regulatory Scrutiny** Commenter states the ISOR summarizes the regulations being proposed for compounded medications evidence, it overlooks significant failures associated with FDA-approved drugs. **Scientific Evidence Supporting Compounded Therapies** Commenter states research strongly supports the safety and efficacy of sterile compounded medications for conditions like ME/CFS and Long COVID. **Impact on Research and Innovation** Commenter states the proposed regulations pose a significant threat to critical research efforts to understand and treat ME/CFS, Long COVID, and related conditions. Sterile compounded medications are essential tools in clinical trials and translational research that seek to unravel the	Double Standards in Regulatory Scrutiny: The Board appreciates the comments and notes the FDA is responsible for the approval of drugs and the regulation of drug manufacturers. Concerns about the regulation of drug manufacturers should be provided to the FDA. The FDA and state boards have shared jurisdiction over compounding with provisions established in federal law, national standards (that must be met as required in federal law) and state law. Scientific Evidence Supporting Compounding Therapies: The Board recommends that the commenter provide this information to the FDA, the agency responsible for evaluating and approving bulk drug substances for inclusion in federal regulation. Impact on Research and Innovation: Board staff note that federal law establishes provisions for clinical research and human drug trials. One good source to learn more about the process is clinicaltrials.gov. Misalignment with Federal Standards: As part of the comments, the commenter suggests that the Board, in developing its regulations has violated the APA process. Board staff respectfully disagree. Staff further note that as part of the proposed regulations, the Board is seeking to provide a legal pathway to compounding using bulk drug substances that have not been approved by the FDA and included in federal regulations, under specified conditions. The Board believes its proposed approach aligns with federal enforcement discretion policies while also providing clear guidance on how to comply with insanitary conditions requirements and USP components requirements. Marginalization of Compounded Medications: Board staff note that public documents from a number of entities including the FDA, ISMP, the Pew Charitable Trust and others have highlighted patient safety concerns with compounded medications. This should not be interpreted as suggesting that compounding cannot be safe. To the contrary, federal law, national standards and Board regulations all seek to promote consumer protection. Overwhelming Public Opposition: Board staff have reviewed the comment and do not recommend changes to the proposed text based on this comment. The requirements for compounding,

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		complexities of these debilitating illnesses. **Misalignment with Federal Standards** Commenter states the proposed regulations exceed FDA guidelines without clear justification, creating duplicative compliance requirements that are costly, impractical, and unnecessary. **Marginalization of Compounded Medications: Protecting Pharmaceutical Interests** Commenter states that framing compounded medications as "risky" or "unproven" appears to protect the market dominance of pharmaceutical companies producing FDA-approved drugs. **Overwhelming Public Opposition** Commenter states that the regulation have faced large-scale and unanimous opposition from all stakeholders, including sitting Board members. **Advocacy for Alternatives and Delayed Implementation** Commenter states that rather than imposing sweeping restrictions, the Board should facilitate safety improvements that preserve access to essential therapies, including exemptions for essential sterile compounded medications such as glutathione, NAD+, and vitamin B12 to maintain access for patients managing debilitating conditions, provide grants or low-interest loans and streamline licensing processes to help pharmacies invest in necessary equipment and facilities without bureaucratic hurdles, offer	whether the national standards or proposed Board regulations, generally elicit significant comments from interested stakeholders. For example, the USP received and responded to 178 comments relating to the development of the USP 795 national standards. The USP responded to each of the comments, accepting some comments, partially accepting some comments and not incorporating some of the comments. The USP received 1,705 comments in response to the development of USP Chapter 797 standards again accepting some comments in full, partially accepting some comments, and not incorporating some of the comments. Regarding the comment that sitting Board members are opposed to the proposed regulations, Board staff note that individual Board members frequently express their concerns in public meetings in response to public comments received. Board staff further note that the power of the Board is vested in the Board itself - which acts by collective decision at a meeting – and does not reside with any individual Board member. The purpose of a Board meeting is to allow for an open and frank discussion about proposed actions. Individuals interested in learning about the Board's discussion and action can view the meetings in their entirety through the livestreams posted on the Board's website. Advocacy for Alternatives and Delayed Implementation: The comments provided in this section do not appear related to the compounding text, but rather are offering recommendations to the Board on its approach to regulation. Commenter is requesting a delay in the effective date of the regulations. The Board has considered delayed implementation and identified specific areas that are appropriate for additional time to comply. In such instances the proposed regulation text reflects additional time to comply. Legal and Ethical Overreach: Board staff respectfully disagree that the proposed regulations represent a violation of established federal standards. The proposed regulations, as with any action taken by the Board, are pursued consistent with its statutory mandate and its rulemaking authority. Upcoming Sunset Review and Oversight Implications: The comments provided in this section of the comment do not appear to be

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		extensive training programs on sterile compounding best practices and provide access to compliance guidelines and technical assistance to uphold high standards, and engage pharmacies, healthcare providers, and advocacy groups in rule-making to develop practical, evidence-based regulations and foster partnerships that support compliance. The commenter states that if the Board proceeds with the regulations, implementing a one-year delay is essential. **Legal and Ethical Overreach** Commenter states that the proposed regulations represent a violation of established federal standards and create unnecessary barriers to care. Restricting essential treatments without evidence of harm, the Board violates the ethical principle of non-maleficence—"do no harm." Commenter states that they are prepared to support legal challenges to ensure compliance with the APA and to hold the Board accountable for advancing regulations that lack evidence-based justification.	related to specific proposed regulation text. Staff note that it looks forward to working with the Legislature and the Administration during the sunset review process. The commenter is requesting five actions from the Board. 1. Reject the proposed regulations. Board staff disagree with this recommendation for numerous reasons detailed in public materials as well as this rulemaking record. 2. Adopt targeted alternatives: The Board has considered all recommendations to changes the proposed regulation text and will continue to do so in compliance with the APA. The Board has made significant changes to the proposed text based on all of the comments. To assist individuals in submitting comments, the Board provided a recommended template for submission of comments. While not required, comments submitted with specific language and details are easier to consider and respond to. 3. Delay Implementation: The Board has considered delayed implementation and identified specific areas that are appropriate for additional time to comply. In such instances the proposed regulation text reflects additional time to comply. 4. Engage stakeholders: The Board has provided numerous opportunities for stakeholders to engage in the process. Board staff note that the development of the proposed regulations have occurred over several years, providing an opportunity for engagement with interested stakeholders. Staff disagree with the assertion that the Board has not engaged with experts. Staff note that two members of the Board are experts in compounding and system implementation. Further, the Board has experts on staff that have been extensively involved in the development of the regulations. In addition, the Board seeks expert advice through a variety of means including experts with a variety of different backgrounds including laboratory experts, veterinary practice, radiopharmaceutical practice, certification of rooms and equipment, other state regulators and accrediting agencies. Further, the Board dedicated significant time to review and evaluation of the USP Chapters along with the FAQs and commentary. The Board also collaborates with the FDA. 5. Ensure Compliance with APA and OAL standards: The Board is following the APA process. Several oversight and control

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			agencies monitor the Board's rulemaking activities and evaluate the Board's actions to ensure compliance with the requirements.