#	Section	Commenter	Comment	Staff Response
1	1735(d)	Novo Nordisk	**Comment:** We support the Board's revisions to the definition of "essentially a copy" in the nonsterile compounding regulations. In particular, the requirement that the prescriber determination of a clinically significant difference for an identified individual patient be verified and documented by the pharmacist is consistent with FDA's 503A Copies Guidance. The agency's guidance provides that a compounder should maintain records to show compliance with section 503A(b)(1)(D) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), which is the restriction on compounding "essentially copies of a commercially available drug product." FDA states in its guidance that, for example, "records should be kept of notations on prescriptions for identified individual patients that a prescriber has determined that the compounded drug has a change that produces a significant difference for the identified patient." Further, we agree that pharmacists should take steps to verify those determinations. The Board's updates to the definition of "essentially a copy" help to ensure that patients receive the benefit of the prescriber determination requirement, which is an important check on the compounding of unapproved compounded drug products. Specifically, the prescriber determination is intended to ensure that compounding of drug products is based on the legitimate medical need of an individual patient. We recommend adding to the definition of "essentially a copy" at Section 1735(d) the requirement that documentation of the prescriber determination be maintained in a readily retrievable format. This requirement was originally at Section 1735.1(e)(1) of the Second Modified Text, and our recommendation in this regard is not intended to make any substantive change to that requirement. Rather, we propose merely to relocate that language as a result of our recommended changes to Section 1735.1(e)(1), described below.	Board staff have reviewed the comment and do not recommend any change to the proposed text. Staff note that proposed regulation Section 1735.14(a) provides that records shall be maintained as required by USP Chapter 795 and this article in a readily retrievable form. The records suggested by the commenter would be covered by the provisions in Section 1735.14(a).

			Recommended language revision: "'Essentially a copy' of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product, except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as verified and documented by the pharmacist, between that compounded preparation and the comparable commercially available drug product. Such documentation must be maintained in a readily retrievable format."	
2	1735(d)	CMA	CMA is concerned that the Board's proposed modified text establishes a new requirement for pharmacists to "verify" that a prescribed compounded drug product produces a clinically significant difference for the medical need of an identified individual patient under specific conditions. CMA acknowledges the role of pharmacists exercising professional judgment, as outlined in Business and Professions Code (BPC) section 4306.5. However, the proposed requirement to "verify" introduces unnecessary and unintended rigidity into the process. Contrary to the Board's assertion, mandating verification in every instance of compounding a drug that is otherwise commercially available and not on a shortage list sets a prescriptive standard for how pharmacists must exercise their professional judgment. The language of the regulations expressly requires pharmacists to verify the existence of a clinically significant difference for each compounded preparation in this situation, rather than allowing pharmacists to exercise their professional judgment as to when such verification may be warranted. This mandate impedes the flexibility the Board claims to seek to preserve and, as such, the language violates the clarity standard because it conflicts with the Board's description of the effect of the regulations in its response above.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that this issue was previously considered by the Board, most recently during the January 8, 2025, Board Meeting. As approved by the Board during the January 8, 2025, board meeting, the second modified text included the requirement that a pharmacist verify that a prescribed medication is clinically appropriate for a patient, irrespective of whether it is a compounding medication.

			Pharmacists are already obligated to exercise judgment when dispensing dangerous drugs and are empowered by BPC section 733(b)(1) to refuse to dispense a prescription based on professional judgment, potential harm, or legal concerns. Eliminating the "verify" requirement from the proposed regulation would not abrogate pharmacists' statutory responsibilities but would instead maintain the flexibility pharmacists need to practice most effectively. The verification requirement would also impose significant administrative burdens on both pharmacists and prescribing physicians. For each compounded medication, pharmacists would need to collect and document proof of verified clinical significance for the prescribed drug, while physicians may be required to provide additional supporting evidence. This process could lead to delays in dispensing compounded medications, creating barriers for patients who rely on these treatments. For some patients, such delays could limit timely access to necessary therapies, ultimately harming their care. Finally, federal law, specifically 21 USC § 353a and 21 CFR Part 216, does not establish a documentation requirement, let alone a verification requirement for compounding. FDA guidance only recommends that "[…] the compounder should ensure that the determination is documented on the prescription." The guidance also clarifies that the FDA "[…] generally does not intend to question prescriber determinations that are documented in a prescription or notation." Current state regulations require pharmacists to retain the documentation of the determination of clinical significance. The Board's proposal, however, goes beyond all of these standards by mandating that pharmacists both verify and document the prescriber's determination. This additional verification obligation introduces a new requirement, not a clarification of existing state or federal statute. By creating this new regulatory standard, the proposal could be interpreted to place	

			an unprecedented burden on pharmacists, that of duplicating the evaluation already made by the prescriber. This shift in legal construction is unnecessary, given that pharmacists are already accountable for using their professional judgment to ensure compliance with established pharmacy laws. For these reasons, CMA recommends deleting "verify and" from proposed sections 1735(d), 1735.1(e)(1)(B), 1736(d), and 1736.1(e)(1)(B) of the second modified text. This would maintain the documentation standard established in current regulation while ensuring pharmacists retain the flexibility to perform verifications as deemed appropriate based on their professional judgment, as intended by the Board.	
3	1735(d)	Wedgewood	Prescribers' submission of a compounded preparation to a compounding pharmacy should be sufficient documentation to that an essentially a copy produces for that patient a clinically significant difference. The current definition allowed a pharmacist to use their professional judgement when determining whether a compound is essentially a copy. While we appreciate that clarity in the notes, the definition remains ambiguous to that intent and as such, we request that a clarifying statement be added to that effect. Without that clarity, enforcement action could be taken against a pharmacist if their professional judgement were called into question. Additionally, we argue that it is a fact, not an opinion, that a licensed prescriber who executes a valid prescription for a compounded medication has made the clinical determination within their scope of practice, expertise, and licensure that the medication prescribed produces a clinically significant difference for that patient. Absent indications within the scope of a pharmacist's licensed scope of practice and professional judgement, a pharmacist cannot be required to make inquiries to the clinical rationale and professional judgement of the prescriber as the pharmacist is neither qualified nor licensed to make such a judgement and even attempting to endeavor	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that this issue was previously considered by the Board, most recently during the January 8, 2025, Board Meeting. As approved by the Board during the January 8, 2025, board meeting, the second modified text included the requirement that a pharmacist verify that a prescribed medication is clinically appropriate for a patient, irrespective of whether it is a compounding medication. Should it be helpful, Board staff refer the commenter to some specific provisions of the law that establish specific requirements for pharmacists to evaluate prescriptions prior to dispensing including as examples:. Health and Safety Code section 11153 Business and Professions Code section 733 Title 16, California Code of Regulations Section 1707.3

			to do so could be characterized as unlicensed and prohibited clinical practice. The Board is not authorized to require pharmacists to exercise clinical judgement outside of the practice of pharmacy.	
4	1735.1	CA Rheumatology Alliance And CA Society of Plastic Surgery	We have reviewed the staff responses to our comments and continue to be concerned with the applicability of the proposed regulations on physicians and their ability to "compound" medications in their offices. Although physicians may not be under the enforcement jurisdiction of the Board of Pharmacy, we believe the proposed regulations would change the standard of care for when physicians compound medications and will not allow rheumatologists/ physicians to buffer injection/ infusion medications in-office. We are interpreting the proposed regulations to require a pharmacist be present or performing the buffering of the injection/ infusion medications. Rheumatology practices/physicians would not be able to afford to employ a pharmacist for this one purpose. This would lead to rheumatology practices no longer offering this service for our patients. Patients would then be forced to obtain their injection/infusions at a hospital or infusion center which would not only be less convenient for our patients, but it would be more expensive for the patient and the overall healthcare system. We believe it is important to note we are not aware of any issues with rheumatologists/physicians "compounding" injection/ infusion medications. We would like to propose the Board of Pharmacy adopt the language suggested by the California Medical Association as shown below: **§ 1735.1:** In addition to the standards in USP Chapter 795 and, Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) the compounding of a CNSP shall meet the following requirements of this article. **This article shall not apply to compounding by or under the direct supervision of a licensed physician and surgeon.**	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment. Board staff note that the Board has previously considered this comment, most recently during the January 8, 2025, Board Meeting and determined that the requested change is not appropriate. 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 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.
5	1735.1	FLAVORx	Recommendation: "A facility that compounds using flavoring agents combined with a prescribed FDA approved drug in an oral liquid dosage form at the request of a prescriber, patient or patient's agent shall be exempt from the requirements established in subdivision (f) and Sections 1735.2 – 1735.13." Dropping the word "limits" clears up the confusion around whether sections 1735.2-1725.13 would apply to all flavorings should a facility also perform	Board staff have reviewed the comment and thank the commenter for highlighting that the second modified text needs clarification. Staff note that the examples provided by the commenter appear to be intending to expand the Board's policy - - limiting the applicability of Board's compounding exemption for a facility that is solely compounding by adding of a flavoring agent. Staff note that if a facility is flavoring a prescription that is reconstituted pursuant to the FDA approved labeling would meet the exemptions

			occasional compounding of Tamiflu, amoxicillin, magic mouthwash, etc.	proposed. However, a facility that compounds, for example, magic mouthwash would NOT be exempt under this subdivision as the facility is NOT limiting its compounding solely to the adding of a flavoring agent. **1735.1(i) A facility that limits its compounding to combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of a prescriber, patient or patient's agent shall be exempt from the requirements established in subdivision (f) and Sections 1735.2 – 1735.13. A facility that performs any other form of nonsterile compounding at any time is not exempt as provided in this subdivision.**
6	1735.1(c)	Marie Cottman	Remove duplication of language "is necessary" because having the phrase twice in the same sentence is confusing. **Recommend revision:** (c) Notwithstanding subdivision (a), a limited quantity of a CNSP may be prepared and stored in advance of receipt of a patient specific prescription document where it is necessary, and solely in such quantity, ~~as is necessary,~~ to ensure continuity of care of individual patients based on a documented history of prescriptions for those patient populations.	Board staff have reviewed the comment. Board staff believe that the language included in the second modified text is clear, however, receipt of this comment suggests otherwise. In response to the comment, Board staff recommend the following change: 1735.1(c) Notwithstanding subdivision (a), a limited quantity of a CNSP may be prepared and stored in advance of receipt of a patient specific prescription document where **it is necessary**, and solely in such quantity**, ~~as is necessary~~**, to ensure continuity of care of individual patients based on a documented history of prescriptions for those patient populations.
7	1735.1(d)	Wedgewood	Based on staff comments an amount of compounded drug may be furnished to a veterinarian based on the estimated need of the veterinarian as submitted on a purchase order will be considered the determination of a reasonable quantity. We appreciate the Board's recognition of Office Use (Stock) as an important service provided by	Board staff have reviewed the comment and do not recommend a change to the proposed text. Board staff believe the proposed modified text is clear when read in its totality. This issue was considered most recently by the Board during its January 8, 2025, meeting. During this meeting the Board approved changes to this section

			pharmacies to veterinary medicine professionals and we appreciate the expansion of the ability to dispense from Office Stock to 14 days. We are concerned about the continuing ambiguity of the phrase "reasonable quantity" as it remains undefined in this draft. We are not opposed to placing limitations, but a lack of definition creates ambiguity, risks inconsistent enforcement, and further calls on pharmacists to exceed their scope of licensed practice. In the Board's response to our comment it was noted, "As the commenter notes, reasonable quantity is further clarified in paragraphs (1) and (2)". We interpret this to mean that the veterinarian's purchase order indicating that the order is for office administration, or application, and for dispensing no more than 14 days' supply constitutes a reasonable quantity and will proceed under that assumption unless further clarity is provided. As such, we will not be required to make a determination of whether the licensed prescriber "fairly estimated" the days' supply ordered.	that were included in the second modified text and allows for a 14-day supply as specified.
8	1735.1(e)	Outsourcing Facilities Assoc.	The proposed amendment should be revised for additional clarity, for the reasons stated below: The proposal demanded that pharmacists engage in the practice of medicine in contravention of California law, imposed obstacles to federal policies under the FDCA in contravention of federal law, and operated in erratic ways for no rational policy objective. The Second Modified Text appears to address OFA's objections or at least those along similar lines by requiring only that a "pharmacist verifies and documents" a clinically significant difference, rather than make the determination of clinically significant difference, which the prescribing practitioner must do under federal law. However, the Second Modified Text of Proposed § 1735.1(e) may fall short of achieving these objectives because it is arguably ambiguous concerning (1) what is to be verified and documented and (2) what verification and documentation is required.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that this issue was previously considered by the Board, most recently during the January 8, 2025, Board Meeting. As approved by the Board during the meeting, the second modified text included a requirement that a pharmacist verify that a prescribed medication is clinically appropriate for a patient. This is consistent with the practice of pharmacy and the requirement extends to all prescriptions, irrespective of whether it is a compounded medication. Board staff note that the commenter appears to suggest 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

			First, the shift from a determination standard to a verification and documentation standard indicates that the pharmacist under the Second Modified Text need only verify and document that a prescribing practitioner has made a finding of clinically significant difference. But there is an arguable ambiguity: the draft text's reference to verifying and documenting directly "that the compounding produces a clinically significant difference" could be misunderstood to require that pharmacists find an actual clinically significant difference in possible conflict with doctors' findings. The text should be revised to make clearer that the pharmacist must verify and document that the prescriber has made such a determination. Second, the Second Modified Text is also ambiguous as to what type of verification and documentation is sufficient. As drafted, the Modified Text of Proposed § 1735.1(e) may be misunderstood to require onerous, impractical, vague, or inconsistent verification and documentation requirements that prove unworkable or overly burdensome in practice. This ambiguity can be resolved by making clear that a pharmacist who verifies, from a notation documented on the prescription itself or other similar communication from the prescriber to the pharmacist, that the prescriber has determined the clinically significant difference of the prescription—and adds a notation to the pharmacist's patient file recording this fact—meets the verification and documentation requirement of Proposed § 1735.1(e). The Board should clarify the text of Proposed § 1735.1(e) along the lines proposed above. At a minimum, it should clarify in the preamble of any final action promulgating this rule or in concurrently issued guidance that, under this provision, a pharmacist need only verify and document that a prescribing practitioner has made a finding of clinically significant difference in the manner described above.	another individual. This is obligation is memorialized throughout Pharmacy Law, including notably BPC Section 4306.5. Should it be helpful, Board staff refer the commenter to some specific provisions of the law that establish specific requirements for pharmacists to evaluate prescriptions prior to dispensing including, as examples: Health and Safety Code section 11153 Business and Professions Code section 733 Title 16, California Code of Regulations Section 1707.3

9	1735.1(e)(1)	Novo Nordisk	**Comment:** We recommend that the Board update Section 1735.1(e)(1) to state only the prohibition on compounding of "essentially a copy of one or more commercially available drug products," as defined at Section 17735(d). The exceptions to the copies restriction at (e)(1)(A) in the Second Modified Text – related to shortage lists and inability of a health care facility to obtain a drug – are overly permissive and inconsistent with federal law and policy. The state regulations, as currently proposed, would allow drugs to be compounded under circumstances that are inconsistent with FDA's current interpretation of Section 503A of the FDCA stated in the agency's 503A Copies Guidance.5 In that guidance, FDA states that the agency does not consider a drug to be "commercially available" within the meaning of the federal copies restriction if it is present on FDA's drug shortage list, and when the drug product has been discontinued and is no longer marketed.6 The Board's proposed regulations go even further, and would also permit compounding of copies when a drug product appears on the ASHP list, and when a health care facility "cannot obtain" a drug from the manufacturer or wholesaler. These broad exceptions are inconsistent with federal law and current policy and could lead to compounding of unapproved drug products when the FDA-approved drugs are available to meet the patients' needs. Thus, the exceptions undermine a key check on compounding of unapproved drug products, posing risks to patient safety and the public health, and should be updated accordingly. Additionally, the requirement in the Second Modified Text that the compounding pharmacist verify and document the prescriber determination of a clinically significant difference for an identified individual patient is duplicative of the requirement stated in the definition of "essentially a copy" at Section 1735(d), and is thus unnecessary. Finally, as described above, we have proposed to add the requirement that documentation of the prescriber determination be maintained in a readily retrievable format to Section	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that the proposed text in 1735.1(e)(2) related to the ability to compound within 60 days of the end of a shortage is consistent with the recent approach the FDA announced regarding the status of the tirzepatide shortage. Further, the Board's provisions specifically include additional flexibilities for health care facilities licensed pursuant to Health and Safety Code 1250 (which include hospitals), is consistent with the FDA's guidance related to compounding a drug that is essentially a copy that acknowledges that the FDA is considering the applicability of its policies described in the guidance document to hospitals and health systems. As the FDA has not released this separate guidance, the Board believes its approach is consistent with the intent of federal law while ensuring hospitals have additional flexibility to take care of patients. Board staff respectfully refer the commenter to the Modified Initial Statement of Reasons that includes the referenced FDA Guidance Document, Compounded Drug Products that Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act.

			1735(d). Therefore, we recommend that Section 1735.1(e)(1) be updated to state only the prohibition on compounding copies, referencing the relevant definition in the regulations. **Recommended language revision:** "(e) In addition to prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, as defined at Section 17735(d) of this article."	
10	1735.1(e)(1)(B)	CMA	CMA is concerned that the Board's proposed modified text establishes a new requirement for pharmacists to "verify" that a prescribed compounded drug product produces a clinically significant difference for the medical need of an identified individual patient under specific conditions. CMA acknowledges the role of pharmacists exercising professional judgment, as outlined in Business and Professions Code (BPC) section 4306.5. However, the proposed requirement to "verify" introduces unnecessary and unintended rigidity into the process. Contrary to the Board's assertion, mandating verification in every instance of compounding a drug that is otherwise commercially available and not on a shortage list sets a prescriptive standard for how pharmacists must exercise their professional judgment. The language of the regulations expressly requires pharmacists to verify the existence of a clinically significant difference for each compounded preparation in this situation, rather than allowing pharmacists to exercise their professional judgment as to when such verification may be warranted. This mandate impedes the flexibility the Board claims to seek to preserve and, as such, the language violates the clarity standard because it conflicts with the Board's description of the effect of the regulations in its response above. Pharmacists are already obligated to exercise judgment when dispensing dangerous drugs and are	Board staff have reviewed the comment and do not recommend a change to the proposed text because modifications in the second modified text addressed it. Staff note that this issue was previously considered by the Board, most recently during the January 8, 2025, Board Meeting. As approved by the Board during that meeting, the second modified text included a requirement that a pharmacist verify that a prescribed medication is clinically appropriate for a patient, irrespective of whether it is a compounded medication. While this commenter has not previously submitted comments in this area, 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. Should it be helpful, Board staff refer the commenter to some specific provisions of the law that establish specific requirements for pharmacists to evaluate prescriptions prior to dispensing including, as examples:

			empowered by BPC section 733(b)(1) to refuse to dispense a prescription based on professional judgment, potential harm, or legal concerns. Eliminating the "verify" requirement from the proposed regulation would not abrogate pharmacists' statutory responsibilities but would instead maintain the flexibility pharmacists need to practice most effectively. The verification requirement would also impose significant administrative burdens on both pharmacists and prescribing physicians. For each compounded medication, pharmacists would need to collect and document proof of verified clinical significance for the prescribed drug, while physicians may be required to provide additional supporting evidence. This process could lead to delays in dispensing compounded medications, creating barriers for patients who rely on these treatments. For some patients, such delays could limit timely access to necessary therapies, ultimately harming their care. Finally, federal law, specifically 21 USC § 353a and 21 CFR Part 216, does not establish a documentation requirement, let alone a verification requirement for compounding. FDA guidance only recommends that "[…] the compounder should ensure that the determination is documented on the prescription." The guidance also clarifies that the FDA "[…] generally does not intend to question prescriber determinations that are documented in a prescription or notation." Current state regulations require pharmacists to retain the documentation of the determination of clinical significance. The Board's proposal, however, goes beyond all of these standards by mandating that pharmacists both verify and document the prescriber's determination. This additional verification obligation introduces a new requirement, not a clarification of existing state or federal statute. By creating this new regulatory standard, the proposal could be interpreted to place an unprecedented burden on pharmacists, that of duplicating the evaluation already made by the	Health and Safety Code section 11153 Business and Professions Code section 733 Title 16, California Code of Regulations Section 1707.3

			prescriber. This shift in legal construction is unnecessary, given that pharmacists are already accountable for using their professional judgment to ensure compliance with established pharmacy laws. For these reasons, CMA recommends deleting "verify and" from proposed sections 1735(d), 1735.1(e)(1)(B), 1736(d), and 1736.1(e)(1)(B) of the second modified text. This would maintain the documentation standard established in current regulation while ensuring pharmacists retain the flexibility to perform verifications as deemed appropriate based on their professional judgment, as intended by the Board.	
11	1735.1(e)(2)	Wedgewood	The reference to a specific edition of a Guidance Document is troubling. Recommendation: This compound shall be in compliance with current industry guidance. the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022. We are grateful for the Board's clarification on the inclusion of the AMDUCA reference. While we appreciate the clarity provided, we are concerned that a direct reference to a Guidance Document (GFI 256), including a specific dated version, could be problematic should that document be modified or repealed. Rather than reference a specific document, we would recommend removing the language or changing it to simply reflect "applicable industry guidance" as noted below.	Board staff have reviewed the comment and do not recommend any change to the proposed text. Board staff note that to meet the requirements of the APA, the proposed regulation text must be sufficiently specific regarding the applicable standards of practice, if those standards are contained in a specific document.
12	1735.3(a)	Marie Cottman	Fix typo: (a) Facilities shall require individuals entering the compounding area to report if the**y have** rashes… (and other grammatical issues) In practice, the supervising pharmacist will not be doing employee inspections looking for rashes, tattoos, or sores. Please remove the requirement for the supervising pharmacist to evaluate for these conditions. **Recommend revision:** (a) Facilities shall require individuals entering the compounding area to report if they have rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection, or any other medical condition, to determine if such condition	Board staff have reviewed the comment. Board staff thank the commenter for highlighting the typographical error. Board staff note that nonsubstantive changes will be made as necessary consistent with the Board's direction to address numbering issues, typos, etc. Board staff believe that the commenter's request to remove the text can be done without risk to patients. In response to the comment, Board staff recommend the following change:

			could contaminate a CNSP or the environment per the facility's SOPs. ~~Prior to admitting any personnel into a compounding area, the supervising pharmacist shall evaluate whether personnel is experiencing any of the above conditions could contaminate a CNSP or the environment.~~ After ~~such~~ evaluation and determination, the supervising pharmacist shall not allow personnel with potentially contaminating conditions to enter the compounding area.	1735.3(a) Facilities shall require individuals entering the compounding area to report **~~to the supervising pharmacist~~** if **~~they have~~** rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection, or any other medical condition, to determine if such condition could contaminate a CNSP or the environment per the facility's SOPs. **~~Prior to admitting any personnel into a compounding area, the supervising pharmacist shall evaluate whether~~** ~~compounding~~ **~~personnel is experiencing any of the above conditions~~** ~~following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection, or any other medical condition, to determine if such condition~~ **~~could contaminate a CNSP or the environment~~** ~~("contaminating condition")~~. **~~After such evaluation and determination,~~** **~~T~~**The supervising pharmacist shall not allow personnel with potentially contaminating conditions to enter the compounding area.
13	1735.3(e)	Marie Cottman	Though USP uses the term "reusable," your original term "Non-disposable" makes much more sense for this additional requirement. A compounder may reuse a mask, paper-gown, or booties during their compounding shift. These items will not tolerate (nor be effectively cleaned) by germicidal agent and IPA. Also the wording of "before **use** by different personnel **use.**" is awkward and confusing. **Recommend revision**: ~~Reusable~~ Non disposable garb and equipment shall be cleaned with a germicidal cleaning agent and sanitized with 70% isopropyl alcohol at least daily and before use by different personnel ~~use before re-use~~.(1) Any reuseable gowns must be laundered, per the facility's SOPs before reuse.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Board staff believe it is appropriate to use the same term that is used in the Chapter.
14	1735.7(c)(1)	PCCA And CSHP	Recommend: We recommend that the clause in Section 1735.7(c)(1) be removed entirely. Rationale: **1. Protection of Corporate Proprietary Information**:	Board staff have reviewed the comment and do not recommend changes to the proposed text. The Board previously considered these comments on several occasions including as part of its discussion

			The identity of the manufacturer of an API is corporate proprietary information and is considered a trade secret for entities such as PCCA. The information holds significant value because disclosing the identity of carefully sourced suppliers would grant competitors a substantial and unfair business advantage. PCCA and other similar businesses, have invested heavily in developing relationships with manufacturers, performing rigorous vetting processes, and ensuring compliance with stringent quality standards. Public disclosure of this information would undermine these efforts and expose suppliers' business models to harm. Suppliers' customarily treat the identity of manufacturers as confidential and provide this information directly to FDA under strict assurances of privacy. The FDA recognizes the sensitivity of this information and allows suppliers to designate it as "confidential" when submitted through the Drug Registration and Listing System. Importantly, the FDA does not release this information publicly in its otherwise comprehensive National Drug Code (NDC) Directory. Similarly, the FDA excludes this information from reports it makes public regarding compounded drug products manufactured by outsourcing facilities. These practices reflect a consistent understanding of the confidential and proprietary nature of this information at the federal level. **2. California State Laws Protect Trade Secrets**: California law explicitly protects proprietary information, including trade secrets relating to food, drugs, and cosmetics. Under the California Public Records Act, Cal. Gov. Code, §§ 6250 et seq., corporate records and trade secrets are exempt from public disclosure. Specifically, § 6254.15 shields "corporate proprietary information including trade secrets." Further, the California Health and Safety Code § 110165 precludes the state from disclosing any information acquired about trade secrets, emphasizing that such proprietary information are entitled to protection. **3. Alignment with Federal Standards:**	during the November 5-6, 2024, Board Meeting. As was noted at that time, Board staff reviewed the comment and do not recommend any changes to the proposed text based on the comments. Staff note that while existing law provides flexibility to record the manufacturer under limited circumstances, continuation of the current provision is not appropriate as it hampers the ability of a facility to respond appropriately in the event of a product recall. Staff further noted that the Board's proposed regulation text is more explicit than the Chapter for the reasons cited elsewhere in this response. Staff note that the Chapter requires either the recording of the manufacturers or vendors; however, in separate guidance issued by the FDA, the facility needs to have transparency into the supply chain and awareness of the manufacturer (where the manufacturer and vendor are different.) The FDA has released guidance in this area, including the importance of compounders knowing their suppliers - - https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipientssuppliers. Lastly, requiring the identity of the manufacturer of a component to a compounder who is compounding with that component without requiring more information be provided does not appear to be requiring the disclosure of a trade secret under Civil Code section 3426.1(d). Moreover, vendors can take steps when contracting with compounders to protect the information related to their business arrangements with manufacturers. Staff refer the commenter to the underlying data portion of the Modified Initial Statement of Reasons, which includes the above referenced FDA guidance document.

			The proposed requirement goes beyond existing federal regulatory standards, including USP Chapters 795 and 797, which do not mandate disclosure of the manufacturer in compounding records. Instead, USP standards require documentation of the lot number, expiration date, and supplier information, which ensures traceability and accountability without risking the exposure of trade secrets.	
15	1735.9(c)	Marie Cottman	**Recommend to remove this section.** This is completely redundant. It just restates laws that already exist. As Compounding CNSPs are drugs, they already require all the labelling specified in 4076 and 1707.5. There is no implied exemption from labelling requirements in USP 795. (If one of your licensees thinks they only have to comply with USP and they can ignore the other body of laws relative to the practice of pharmacy in CA, you will have much bigger problems than the label.)	Board staff have reviewed the comment and recommend a change to the proposed text. Staff agree with the commenter's suggestion that even with deletion of the language, the requirements to comply with BPC 4076 and CCR section 1707.5 would continue to be relevant. Staff offer the following recommendation: ~~(c) The label for any Any CNSP dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5. A CNSP that is administered to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility, or a juvenile detention facility shall be labeled with patient name, the directions for the use of the drug, and date of issuance, but is otherwise exempt from these requirements.~~
16	1735.10(b)(1)	Marie Cottman	This proposed rule is far too restrictive. What if no data exists? The study to determine chemical and physical stability data is literally $30,000 or more! Under this rule, when a prescriber is identifying a novel drug delivery solution for a unique patient experience, compounders will be unable to compound a new preparation because there is no existing DATA to demonstrate stability. Even if the pharmacist were to apply a conservative 14 day refrigerated BUD, without data, they would be in violation of this rule and	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff believe the commenter may be referring to stability of the end product. Staff believe the Chapter is referring to physical properties of an individual API. Staff note that all APIs affect quality and pursuant to the provisions of the Chapter, a compounder must therefore consider the chemical and physical stability of the API and any

			subject to action against their license. *This will limit access to potential solutions for patients with unique needs!* USP 795 Chapter 10 allows for considerations to be used in determining a BUD, which MUST be conservative. **Recommend to remove this section (USP already addresses what to consider when determining BUDs.) If you won't remove it, allowing recommendations in USP to stand on their own merit, then please consider rewrite:** *(b) A CNSP's BUD shall be conservatively assigned when data is not readily available to validate chemical and physical stability or compatibility and degradation with the container-closure system.*	added substance. It appears the commenter is suggesting that such information may not be available in all circumstances. Staff note that APIs are generally sold with this information available. Neither the Chapter nor the Board's proposed regulation text are requiring testing; rather, the compounding pharmacist may rely upon data that is available.
17	1735.10(b)(2)	Marie Cottman	I have concerns that the inspectors could abuse this rule because it is not clear who has the burden of proof that the CNSP is non-reactive with the container- closure system. And again, the testing to provider proof is many $1,000s! Under this rule, when a prescriber is identifying a novel drug delivery device for a unique patient experience, compounders will be unable to package the compound they don't have proof (even if there is good similar data available). If the pharmacist were to apply a conservative 14 day refrigerated BUD, without specific data, they could be in violation of this rule and subject to action against their license. *This will limit access to potential solutions for patients with unique needs!* **Recommend to remove this section (USP already addresses what to consider when determining BUDs.) If you won't remove it, allowing recommendations in USP to stand on their own merit, then please consider rewrite:** *(b) A CNSP's BUD shall be conservatively assigned when data is not readily available to validate chemical and physical stability or compatibility and degradation with the container-closure system.*	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that the proposed regulation text does not require a compounder to perform testing; rather, the compounder must rely on data available to make a determination.
18	1735.11(a)(2)	Novo Nordisk	**Comment:** Aligned with our comments for sections 1735.2(b) and 17.35(c) below, we recommend that	Board staff have reviewed the comment and do not recommend any changes to the proposed text based

			the Board reinsert reference to adverse drug experiences, as specified below, to ensure SOPs state that the pharmacist is responsible for reviewing complaints related to potential quality problems and adverse events. We also recommend that the Board require that SOPs describe written procedures for the surveillance, receipt, evaluation, and reporting of adverse drug experiences. Compounding pharmacies are not held accountable by FDA for any pharmacovigilance obligations. As such, they likely do not have the policies and procedures in place to conduct pharmacovigilance, including to ensure that adverse event reports are shared with the Board and FDA and to assess adverse event reports and take corrective action. A requirement for SOPs to include written procedures related to adverse drug experiences will help compounding facilities implement the Board's quality assurance and quality control provisions. Such a requirement also will ensure that compounding facilities are taking steps to protect patients from unnecessary harm from the use of unsafe and unapproved compounded products, as we describe further below. **Recommended language revision:** "(F) The pharmacist responsible for the review of all complaints related to a potential quality problem with a CNSP and all adverse drug experiences in the event the PIC is not available within 72 hours of the receipt of the complaint or occurrence." *[NEW]* "(H) Written procedures for the surveillance, receipt, evaluation, and reporting of adverse drug experiences to the Board."	on the comment received. The Board's compounding regulations establish the minimum standards for compounding. While staff agree that written procedures for surveillance, receipt, evaluation and reporting of adverse drug experiences to the Board may be appropriate for some facilities, it does not appear necessary for smaller pharmacies such as those that only perform nonsterile compounding of products such as magic mouthwash. When the reporting issue was discussed during the November 5-6, 2024, Board Meeting, members determined that a new reporting requirement to the Board was not necessary for nonsterile compounding.
19	1735.11(a)(2)(C)	Marie Cottman	Chapter 795 Section 6.2.3 already addresses evaluation of a component prior to use (compounding). It specifically states: "Before use, compounding personnel must visually re-inspect all components. Each packaging system must be inspected to detect any container breakage, looseness of the cap or closure, or deviation from the	Board staff have reviewed the comment and disagree that the proposed language is redundant. Staff note that the proposed regulation text focuses on how a pharmacist, overseeing compounding, would identify and catch errors involving the use of inappropriate ingredients prior to compounding.

			expected appearance or texture of the contents that might have occurred during storage. Compounding personnel must ascertain before use that components are of the correct identity based on the labeling and have been stored under required conditions in the facility. If the identity, strength, purity, and quality of components intended for preparation of CNSPs cannot be verified (e.g., containers with damaged or incomplete labeling), the components must be immediately rejected. Any component found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal. 1735.11(a)(2)(C) is redundant and unnecessary. **Recommend to remove.**	Staff note that regrettably many compounding errors stem from compounding personnel using inappropriate ingredients when compounding. Ensuring a method exists that pharmacists follow to ensure compounding personnel are using the correct ingredients in the compounded preparation is necessary to prevent harm.
20	1735.11(a)(2)(D)	Marie Cottman	have additional SOPs addressing all the requirements in this chapter. **Recommend to remove or rewrite:** (a) The facility's standard operating procedures (SOPs) for nonsterile compounding shall be followed and shall: (1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. (2) ~~Also describe the following:~~ Comply with the additional requirements described in this chapter. (~~2~~3) Also describe the following: (leave other lettered items) ~~(D) The method for complying with any other requirements specifically required to be addressed in the facility's SOPs as described in this article.~~	Board staff have reviewed the comment. Board staff agree with the commenter that the language can be removed. Staff recommend the following: 1735.11 ~~(a)(2)(D) The method for complying with any other requirements specifically required to be addressed in the facility's SOPs as described in this article.~~
21	1735.11(b)	Marie Cottman	I really don't think you want to open this can of worms. Potential quality problems are not ACTUAL quality problems. If a patient calls and complains that their bleaching cream is not working after 4 weeks… is that a potential quality problem? It could be, but it also might be that they didn't allow enough time (8-12 weeks to see results), or they just cannot see the	Board staff have reviewed the comment and note the commenter may be referring to proposed regulation text CCR section 1735.12(b). Board staff have reviewed the comment and do not recommend a change to the proposed text. The proposed regulation text require notification specifically regarding a complaint of a potential quality problem or an unexpected ADE. Board staff note that it is

			subtle results, or they left the product at room temperature when it should have been refrigerated, but they are too ashamed to tell you so. Either way, since it COULD be a Potential quality problem, I would report it. I don't have a problem with sharing a TRUE quality issue— topical preparation caused a skin infection, oral medication got moldy before the BUD, an MBK suppository crumbled and could not be used… but what does the Board define as a potential quality? The existing complaint programs and BPC section 1711 already have documentation/evaluation requirements. **Recommend to remove or rewrite with clarity of what you really want to be reported.**	important for the Board to receive complaints of potential quality problems so it is aware of potential and actual quality problems with CNSPs to monitor for patient harm and ensure appropriate action is taken to protect patients.
22	1735.12(a)	Marie Cottman	For clarity, **Recommend adding location of section 1711:** (a) The facility's quality assurance program shall comply with BPC Title 16, section 1711 and the Recalls, out of spec results are NOT scheduled. **Recommend to remove the word scheduled.** …In addition, the program shall include a written procedure for ~~scheduled~~ action, such as a recall, in … (this is also consistent with a change made in proposed rule 1736.18)	Board staff have reviewed the comment and thank the commenter for highlighting that the language may require amendment to provide clarity. Board staff recommend the following change: 1735.12 (a) The facility's quality assurance program shall comply with section 1711 and the standards contained in USP Chapter 1163, ~~entitled~~ *Quality Assurance in Pharmaceutical Compounding*. In addition, the program shall include ~~**the following:**~~ ~~**A a**~~ written procedure for ~~**scheduled**~~ action, such as a recall, in the event any compounded drug preparation is discovered to be outside the expected standards for integrity, quality, or labeled strength.
23	1735.12(b)	Novo Nordisk	**Comment:** We appreciate the Proposed Rule's quality assurance and quality control provisions to address quality issues with compounded nonsterile products. Aligned with our comments for section 1735.12(c) below, we recommend that the Board reinsert reference to adverse drug experiences, as specified below, to ensure that compounding facilities are required to notify the Board of adverse events involving nonsterile compounded products. Unlike sponsors of FDA-approved medicines that are subject	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comment received. The Board's compounding regulations establish the minimum standards for compounding. When the reporting issue was discussed during the November 5-6, 2024, Board Meeting, members determined that a new reporting requirement to the Board was not necessary for nonsterile compounding.

			to expansive postmarketing reporting of adverse drug experiences,7 compounding pharmacies do not do surveillance, evaluation, or reporting of adverse events to FDA. In the wake of unprecedented demand for GLP-1 medicines, compounding facilities are mass marketing unsafe and unapproved compounded "semaglutide" products to patients, raising the risks of adverse events that go unreported. The rampant compounding of "semaglutide" is putting patients at risk. FDA's adverse event reporting system ("FAERS") database shows that 619 adverse events, including 144 hospitalizations and 12 deaths, have been reported to the Agency following use of a compounded "semaglutide" product.8 This is more than double the number of adverse events that FDA received for all compounded drugs in 2022.9 Yet the adverse events reported in FAERS are expected to be only a small portion of the adverse events patients are experiencing after taking compounded "semaglutide." Indeed, FDA has stated that "it is likely that adverse events from compounded versions of these drugs are underreported,"10 underscoring the importance of the Board instituting a requirement that compounding facilities report all adverse events associated with compounded products to the Board. **Recommended language revision:** "The Board shall be notified in writing within 96 hours of the facility's receipt of a complaint of a potential quality problem or the occurrence of an adverse drug experience as defined in 21 CFR 310.305(b) involving a CNSP."	It appears appropriate to note that the example cited by the commenter appears to be related to a sterile compounded product.
24	1735.12(c)	Novo Nordisk	**Comment:** Building on our comments for section 1735.12(b) above, we recommend that the Board reinsert reference to adverse drug experiences, as specified below, to ensure that compounding facilities are required to review adverse events involving nonsterile compounded products along with other quality problems as specified in the Proposed Rule.	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comment received. The Board's compounding regulations establish the minimum standards for compounding. When the reporting issue was discussed during the November 5-6, 2024, Board Meeting, members

			It is essential that compounding facilities review quality problems and adverse drug experiences to protect patients from unnecessary harm. Testing results have shown that certain compounded "semaglutide" samples have substantially lower or higher strengths than labeled. Testing results from compounding pharmacies marketing sublingual semaglutide products reveal high levels of impurities and inconsistencies between the labeled strength and calculated semaglutide content. One compounded sublingual "semaglutide" sample contained 170% of the labeled strength, while testing results from a different pharmacy's compounded sublingual "semaglutide" contained only 42% of the labeled strength. Some of these compounded sublingual samples had total impurities up to 41% of the sample. Subpotent and superpotent samples pose serious risks to patients. The reduced strength of compounded semaglutide formulations render such products potentially less effective than the FDA-approved semaglutide products. On the other hand, administering too much compounded semaglutide could lead to serious adverse events or even hospitalization, especially if the patient accidentally overdoses on a superpotent product. These differences and inconsistencies illustrate that compounding semaglutide dosage forms is a complex endeavor and are likely to lead to an adverse effect on the safety and efficacy of the drug products. Compounding facilities should take steps to address this growing and present risk posed by compounded drugs. Doing so requires that compounders assess reports of quality problems and adverse events and take corrective action. By reinserting reference to adverse drug experiences, the Board can ensure that compounders assume this responsibility to protect patients. **Recommended language revision:** "All complaints made to the facility related to a potential quality problem with a CNSP and all adverse drug experiences shall be reviewed consistent with	determined that a new reporting requirement to the Board was not necessary for nonsterile compounding. Staff note that the proposed regulation text requires the pharmacy to develop a procedure and identify actions to be taken when a CNSP is discovered to be outside the expected standards for integrity, quality, or labeled strength. Further, the proposed regulation text requires a facility to review all complaints made to the facility related to potential quality problems with a CNSP, with actions to be taken as defined in the SOPs.

			the facility's SOPs within 72 hours of receipt of the complaint or occurrence of the adverse drug experience. Such a review shall be documented and dated as defined in the SOPs."	
25	1735.13	Marie Cottman	This is redundant because it is already required by 795. USP 795 13.1 Packaging of CNSPs states: "The facility's SOPs must describe packaging of CNSPs. Personnel should select and use packaging materials that will maintain the physical and chemical integrity and stability of the CNSPs. Packaging materials must protect CNSPs from damage, leakage, contamination, and degradation, while simultaneously protecting personnel from exposure. And 13.2 Transporting of CNSPs "If transporting CNSPs, the facility must have written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed." **Recommend to remove.**	Board staff have reviewed the comment and do not recommend changes to the proposed text. The proposed regulation text ensures the facility establishes specific SOPs for storage, shipping containers and temperature sensitive CNSPs.
26	1735.15	Marie Cottman	Since compounders who only add flavoring are exempt from 1735.2-1735.12, they would not be required to comply with 1735.12, reporting quality issues. **Recommend adding an SOP requirement similar to 1735.12**	Board staff have reviewed the comment and thank the commenter for the recommendation. An example of a quality problem could include a suspension that appears to become clumpy and/or nonuniform. Board staff recommend the following change: **1735.15(a)(7) Provisions for reporting to the Board the facility's receipt of a complaint of a potential quality problem involving the CNSP. At a minimum the provisions shall require notification to the Board within 96 hours of receipt of a complaint.**
27	1735.15	FLAVORx	Current Text: (a) In addition to the standards in USP Chapter 795 and the Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) a facility that limits its compounding as described in Section 1735.1(i) shall establish the following SOPs: The underlined text infers facilities would need to comply with USP 795 standards in order to flavor	Board staff have reviewed the comment and do not recommend a change in the proposed text. Staff note that recommended changes in section 1735.1(i) will address the issue raised by the commenter.

			medications. If that is the Board's intention, then the exemptions spelled out in 1735.1 (i) will not bring flavoring back to California's pharmacies. The application of USP 795 standards to the practice of flavoring is what drove pharmacies away from providing the service. If that is not the Board's intention, then one possible solution is to remove that reference and go with: "(a) a facility that limits its compounding as described in Section 1735.1(i) shall establish the following SOPs:"	
28	1735.15(b)	CVS	CVS Health greatly appreciates the collaboration that has led to numerous changes in pending language throughout this promulgation. Commenter recommends changing "on the prescription record" to "in the compounding record" to harmonize terminology, reduce confusion, and streamline operations. The commenter believes this requested change to be merely stylistic, and thus acceptance would not necessitate an additional comment period. (b)A pharmacist may compound by combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of the patient or patient's agent without consultation with the prescriber or the prescriber's authorized agent. A pharmacist performing such compounding must document the compounding ~~on~~ in the ~~prescription~~ compounding record.	Board staff have reviewed the comment and believe the recommendation by the commenter is acceptable; however, staff believe flexibility needs to be provided to allow the pharmacy to determine how it will operationalize the documentation requirement. Board staff is offering the following language: **1735.15(b)A pharmacist may compound by combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of the patient or patient's agent without consultation with the prescriber or the prescriber's authorized agent. A pharmacist performing such compounding must document the compounding ~~on~~ in the prescription or compounding record.**