#	Section	Commenter	Comment	Staff Response
1	1735(d)	Eli Lilly	Some of the Board's proposed revisions to the defined term "essentially a copy" are necessary and appropriate to ensure that patients are treated with a compounded drug only when those patients cannot be served by an FDA-approved medicine. The "essentially a copy" ("EAC") prohibition is one of the key legal prohibitions that prevents compounding pharmacies from selling knockoffs of FDA-approved medicines. For it to serve its intended purpose (which is to prevent end runs around the new drug approval requirement in the guise of compounding), the EAC prohibition must be broad and must not be easily evaded. To that end, Lilly offers the following comments. 1. We applaud the Board's proposal to define "essentially a copy" to include any compounded drug "that includes the same active pharmaceutical ingredient(s) (API(s))" as an approved medicine. This broad definition will ensure that the EAC prohibition protects the public health as it was intended by ensuring that compounding pharmacies cannot evade the prohibition through minor or pretextual formulation changes. 2. We also applaud the Board's proposal to limit the exception to the EAC prohibition to situations where the pharmacist has "verified and documented" that the compounded drug will produce a "clinically significant difference" for the specific patient. This verification also is essential to protect the public health and prevent evasion. All too often, providers and pharmacists (often working together pursuant to contracted commercial arrangements) have attempted to evade the EAC prohibition through sham prescriptions and other illicit measures. Requiring the pharmacist to use his or her professional judgment to verify that the compounded drug makes a real change that will be clinically significant will help to ensure that patients receive FDA-approved medicines whenever possible.	Board staff thank the commenter for the information that is in support of the Board's proposed modified text. Board staff have reviewed the comments and do not recommend any change to the proposed text of the regulation.

			We support the Board's proposed revision as it provides the necessary and appropriate flexibility for pharmacists to use their professional judgment in determining whether a compounded drug is essentially a copy. Contrary to the suggestion by other commenters, exercising that professional judgment does not impinge a prescriber's judgment, but rather preserves the ability for pharmacists to exercise their clinical judgment as well. As the Board has previously observed, federal law requires that the compounded drug produce a significant difference for the patient. The proposed revision makes it clear that the pharmacist must independently verify, and then document, that the compounded drug will indeed produce a clinically significant difference from an FDA-approved medicine for a given patient.	
2	1735(d)	CMA	CMA remains concerned that the Board's new proposed requirement for pharmacists to "verify" that a compounded drug produces a clinically significant difference for a patient creates an undue burden and restricts the professional judgment the Board intended to preserve. Mandating verification for every instance of compounding a commercially available drug that is not on a shortage list establishes a rigid, prescriptive standard. This contradicts the Board's stated goal of maintaining flexibility, and, as such, the language violates the clarity standard because it conflicts with the Board's description of the effect of the regulations in its formal response to members of the public regarding this issue. Pharmacists are already required to use their professional judgment in dispensing compounded drugs. 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. As written, the requirement could be interpreted to mean pharmacists must contact prescribers for verification in all cases where they compound a commercially available drug, leading to unnecessary delays in patient care. As a result, the lack of clarity within this requirement risks limiting access to necessary treatments, particularly in cases where compounded medications are essential alternatives to commercially available drugs. Federal law does not impose a verification or documentation requirement on pharmacists. Instead, the FDA, in non-binding guidance, recognizes	Board staff note that the comment does address modification made in the third modified text. Board staff also note that the Board has previously considered this and similar comments and determined that a change was not appropriate. As an example, Board staff respectfully refer the commenter to the Board's prior response to this comment from this commenter in row 2 available here, that says: "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."

			documentation of a prescriber's determination as sufficient. The Board's proposal, by contrast, creates a new obligation without clear justification, increasing administrative complexity without improving patient safety.	
3	1735(d)	CSHP	We add our voice to others who commented on this section who pointed out their concern with the wording of this section. We appreciate the board's position that the intent is to rely on the professional judgement of the pharmacist. At the same time, we object to the wording of the regulation and wish to point out that this section has the potential to be misinterpreted as written, both currently and in the future. It is important to get this right so that the intent is clear and does not cause confusion. The wording of ""Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product," could be interpreted to mean that ANY compound being made is defined as essentially a copy of a commercially available drug product. The trouble here is that any compounded drug that has the same API as a commercially available drug product will violate this regulation. Using the example of a hospital pharmacy that compounds 10 bags of Oxytocin 30 Units in 500ml Normal Saline for use in their Labor and Delivery (L&D) unit. The Oxytocin bag is made by using three 1ml vials of Oxytocin 10units/1ml. By the definition above, it will be a violation of this proposed regulation since these bags are made in bulk and they include the same API as the commercially available drug product of Oxytocin 1ml. These bags are made in bulk, so, by definition, it is not being compounded specifically for an identified individual patient that produces for that patient a clinically significant difference. These bags are being used for almost every patient that will have a delivery on the unit, so one cannot argue that it is being made for a specific individual patient. This proposed regulation, if it is read simply for the way it is stated, will imply that the pharmacist verifying the order will need to go through a process of verifying with the prescriber and then documenting each and every order for Oxytocin bags that the change from the commercially available 10 unit per 1ml vial to a compounded 30 unit per 500ml Oxytocin bag	Board staff note that the comment does address modification made in the third modified text. Board staff note that the commenter appears to be describing what would be considered sterile compounded preparations. The Board notes that the FDA guidance does not address the practice described by the commenter. The Board's proposed regulation text provides greater flexibility to pharmacists in the healthcare setting where the FDA guidance is silent. The Board also refers the commenter to the provisions included in 1735.1(e)(1)(A) that provides additional flexibilities for health care facilities.

			produces a clinically significant difference for each individual patient. In the ISOR, the board states that the FDA guidance document is being utilized to provide guidance regarding this definition (ISOR section copied herewith for reference). It is important to note that the definition taken from the FDA guidance document and used in this proposed regulation, is only one part of three of the definition in the guidance document. Herewith the guidance document section on "Essentially a Copy" for reference: FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if: • the compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product; • the API(s) have the same, similar, or an easily substitutable dosage strength; and • the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug, unless, as provided by section 503A(b)(2), a prescriber determines that there is a change, made for an identified individual patient, which produces, for that patient, a significant difference from the commercially available drug product. The proposed regulation definition crucially leaves out the requirements for a same or similar dosage strength and route. By leaving out these clarifying terms, the definition is now so broad that it is inclusive of every single non-sterile and sterile compound being compounded by a pharmacy in the state of California. From our example above, it is open to interpretation by both the regulated public and board staff of what "essentially a copy" is because it will be everything with the same API. By the proposed definition, since diazepam tablets are commercially available, a pharmacy may not compound a diazepam drip from IV vials since the tablets contains an API that is commercially available (even though it is available in a completely different non-sterile dosage form). According to the definition, a hospital making a batch of oral suspension from tablets on a regular basis for its neonatal of pediatric unit, will be making essentially copies of the API in	

			the tablets and will have to call and verify with the prescriber and then document the self-evident information that the change was made for each and every identified individual patient that produces for that patient a clinically significant difference. We are sure that we can all agree that this is not the intent of the regulation. By adding the crucial elements of strength and route it narrows the definition and it is much clearer and is aligned with both the FDA and board's intent. This addition of language provides clarification while still allowing flexibility for the pharmacist to use professional judgement. By adding the components that aligns with FDA guidance, it becomes clear that it will the same as federal statute and guidance, and we recommend that this regulation be deleted. While all involved currently in the creation and comments for the definition of "essentially a copy" may have a grasp and understanding of the intent of this proposed regulation, we must take the multiple comments from all stakeholders as an indicator that there will be future misunderstanding and misinterpretations of this language. It is of the utmost importance to recognize that ten to fifteen years from now these interpretations and intent will be forgotten, and the only guidance left to enforce are the words as written. We are sure that the current board would not want future board members and staff to enforce this rule under the misunderstandings that we and others took great pains to point out at this moment in time. Recommendation: (d) "Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product, **the API(s) have the same, similar, or an easily substitutable dosage strength; and the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug** except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as **verified and documented** by the **pharmacist**, between that compounded preparation and the comparable commercially available drug product.	

4	1735(e)	Sutter Health	The recommendation reiterates concerns about California's definition of "essential copy" in hopes of further providing detail of the broad definition and the impact. The Board aims to align with the federal 503A standard, but the nonspecific definition lends to comprehensive noncompliance and does not capture the compounding activities which the Board intends to take regulatory action on. According to section 207.3(a)(4) of title 21 of the Code of Federal Regulations, compounding "essentially a copy" involves using bulk drug substances (APIs), not finished drug products. The current and proposed California definitions exceed federal 503A exemptions, especially within healthcare facilities, creating compliance issues. In a medium to large California hospital, compounding pharmacies prepare over 1,000 patient-specific compounds daily under USP 797 standards. These compounds, sharing APIs with commercial products, are deemed "essential copies" under California's restrictive code, requiring extensive documentation for each patient, which is impractical and not the intent of the Board to regulate the activities within scope of the existing and proposed definition. The California Board's definition does not align with FDA's 503A exemption, which allows professional judgment. The state's definition demands documentation of clinical differences for every compound, unlike the federal standard. Examples of discrepancies include: 1. Vancomycin oral solution (DIFICID) for C. difficile treatment, vancomycin lyophilized sterile powder vials, and vancomycin premix IVPB Xellia bags with PEG all share the same API. Compounding a weight-based IVPB for surgical prophylaxis in orthopedic surgery the day prior to anticipated need for intravenous therapy is compounding an essential copy under the CA definition but not under the FDA. 2. Cefazolin oral suspension (FDA-approved dosage form) shares the same API as cefazolin 2-gram sterile lyophilized powder. 3. Vasopressin premix bags of IV solution and the FDA-approved vials of vasopressin solution with an FDA-approved package insert that details making an IV infusion is compounding an essential copy.	Board staff believe the commenter is referring to Section 1735(d). Board staff note that the comment does address modification made in the third modified text. This comment has been previously considered during the 45-day comment period. At that time the Board responded, "Board staff have considered the comment and do not recommend a change to the proposed text. Staff note that as written, the language provides flexibility for a clinician to use their professional judgment when determining if a compound is essentially a copy. Should the Board amend the language to include the recommended language, the Board would be limiting this flexibility and a clinician's professional judgment." The Board also refers the commenter to the provisions included in 1735.1(e)(1)(a) that provides additional flexibilities for health care facilities.

			4. Creating clonidine oral suspension compound for a neonate shares the same API as clonidine tablets. 5. Repackaging a Zosyn premix IVPB product into a syringe to administer to a neonate is defined in CA as an essential copy. 6. Compounding Daptomycin lyophilized powder sterile vial to compound rather than the Baxter premix Daptomycin vial. The California Board should adopt either the FDA's definition or clarify the specificity of API/bulk drug substance compounding to provide clear expectations and enforcement standards to support the necessary compounding practices. The current regulation is impractical and burdensome, forcing hospitals to violate the law, lack clarity or over-document. Updating the definition to reflect safe, practical compounding under the federal 503A exemption is essential. Let's establish a meaningful, enforceable standard.	
5	1735.1	B. Go	The response by the Board that both proposed as well as existing regulations on compounding, as currently worded, do not infringe on the practice of compounding by non-pharmacist licensees under the jurisdiction of other California professional boards, is not satisfactory for the following reasons: 1. You responded with comments from only one board, the Medical Board of California, which only regulates MD's. This does not apply to other licensees such as DO's, nurses, ND's, dentists, and veterinarians, who may also have the right to compound medications in-office without a pharmacist and without interference by the Board of Pharmacy. Furthermore, even the MD's right to compound is still in jeopardy based on current wording of the Board's regulations, for the following reasons: a. The Medical Board's letter noted that only the Medical Board has the right to discipline its licensees. This would only apply if the licensee was being disciplined as an MD, not if they were being disciplined as a person practicing pharmacy without a license. Again as previously stated, the Board of Pharmacy's jurisdiction is to regulate the practice of pharmacy, and therefore practicing pharmacy without a license would fall within their purview. Both currently existing	Board staff have reviewed the comments and do not recommend any changes to the proposed text based on the comments received. Board staff note that the comment does address modification made in the third modified text. The Board has previously considered this and similar comments and provided responses throughout the rulemaking, including for example the response, "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 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

			regulations as well as the proposed changes exclude non-pharmacists from being able to compound, specifically defining the practice of compounding as that which occurs by a pharmacist ONLY. (See proposed regulation 1736.1a (a): "For the purposes of this article, sterile compounding occurs, by or under the direct supervision and control of a licensed pharmacist, pursuant to a patient specific prescription, unless otherwise specified in this article." And see currently existing regulation: CCR 1735(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist") b): The Medical Board's letter notes: "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." - they admit that your regulations may affect MD's practice of compounding. I'm not sure why you have so much resistance to adding wording which would only help to clarify the limitations of your role, and would limit the confusion and ambiguity which the current wording is creating. Instead, you have specifically chosen to include wording which is overly broad, and which implies that compounding only may be performed by a pharmacist. 2. You claim that regulations specifically state you cannot regulate other practitioners 3. Furthermore, you have not directly responded to previous comments that noted the contradiction between your stance on the above and the fact that you are currently making preparations to attempt to regulate what you refer to as 'IV hydration clinics'. These clinics do not have pharmacists, however they do have other non-pharmacist licensees who have the right to compound. The term 'IV hydration clinic' itself is not well-defined by the board, and it is foreseeable that the board could choose to include any medical office that provides IV hydration or IV nutrients in this category, offices in which compounding might be conducted by any of a variety of types of licensed non-pharmacist practitioners who should	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." The Board respectfully refers the commenter to Business and Professions Code section 4170 as well as the Board's jurisdiction. The Board also recommends that the commenter review the Board's Initial Statement of Reason that describes the Board's jurisdiction to gain a better understanding of the applicability of the Board's regulations. The commenter also appears to be providing comments about a statutory proposal related to the regulation if IV hydration clinics. Staff refer the commenter to the Board's proposed statutory proposal for an understanding of the Board's legislative proposal. Staff note that the language in the statutory proposal does include explicit language that it would not apply to a facility for which a professional director is on site while sterile compounding occurs.

			not be under the purview of the Board if it were not for the current language in your regulations. Therefore, the claim that your compounding regulations do not or will not interfere with compounding by non-pharmacist licensees in disingenuous. Please do note and respond to this paragraph in full in your reply as well.' Given all of the above, I recommend you add the following or similar wording somewhere within Title 16 CCR: "The regulations in Title 16 CCR Sections 1735 et seq, 1736 et seq, 1737 et seq, and 1738 et seq do not in any way apply to the practice of compounding by non-pharmacist licensees who have the right to compound based on their own practice act." If however, you do want to have the ability to regulate non-pharmacist licensees, and are therefore unwilling to add the above language, it is imperative that you change all language in the current and proposed regulations that limit compounding to pharmacists alone - including the statement that compounding occurs by pharmacists only, and any language that requires you to have a pharmacist-in-charge in a facility that performs compounding.	
6	1735.1(d)(2)	K. Scott Guess	In my first public comment, I criticized the Board for duplicating much of what was already published by the United States Pharmacopeia (USP), and adding costly extra, and, in my opinion, unnecessarily complicating processes that did not appear to add to patient protections. Though not perfect I must complement the Board for taking into consideration the large number of public comments it received and crafting a much better, more concise set of regulations. What is the purpose for restricting veterinarian office use medications to 14 days? There is no reason why veterinarians should not be afforded the same office use parameters as human practitioners under CCR 1735.2[c][1], sub section [3] seems to imply that veterinarians are a lesser class of prescriber.	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comment received. It does not appear the commenter is recommending any changes to the proposed text. Board staff refer the commenter to 1735.1(d)(1) related to veterinarian office use provisions that do not include a day's supply limitation for office use provisions. Board staff note that the commenter may not be drawing the distinction in the regulation specifically related to these provisions that are separate, 1) provisions for in office use and 2) for dispensing by the veterinarian.

7	1735.1(e)	Outsourcing Facilities Assoc.	The proposed amendment should be revised for additional clarity. The December 2024 comment explained, inter alia, that a requirement that a finding of clinically significant difference be made by "the prescribing practitioner," "the compounding pharmacist," and "the dispensing pharmacist(s)" was arbitrary, capricious and contrary to law. 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 of Proposed § 1735.1 avoids demanding that pharmacists practice medicine 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. With the text so understood, the objections stated in the December 2024 Comment would be resolved. 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. 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, which would raise all the flaws identified in the December 2024 Comment and be unlawful on the grounds stated there. 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 arguably ambiguous as to what type of verification and documentation is sufficient. As drafted, the Modified Text of Proposed § 1735.1(e) may be	Board staff have reviewed the comment and do not recommend a change to the proposed text. Board staff note that the comment does address modification made in the third modified text. This comment was previously considered by the Board. Board staff refer the commenter back to the Board's prior response to this comment included in row 8 available here that included, "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 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

			misunderstood to require onerous, impractical, vague, or inconsistent verification and documentation requirements that prove unworkable or overly burdensome in practice. That, again, would raise all the flaws identified in the December 2024 Comment. This ambiguity can be resolved, however, 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 Third Modified Text, published on or about February 6, 2025 does not address the ambiguity or flaws identified. 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. Furthermore, to ensure consistent implementation, OFA strongly encourages the California Board of Pharmacy to draft a Frequently Asked Questions (FAQ) document, as previously requested by stakeholders, to address and clarify any potential ambiguities surrounding the verification and documentation requirements. This FAQ will provide critical guidance for both prescribers and pharmacists, helping to prevent misunderstandings and ensuring patients receive safe and effective compounded medications under the new regulatory framework	Business and Professions Code section 733 Title 16, California Code of Regulations Section 1707.3"
8	1735.1(e)(1)	Partnerships of Safe Medications	**5. The determination of medical need for a compounded medication should involve the prescribing practitioner** o The proposal to remove the tripartite requirement that the prescribing practitioner, the compounding pharmacist, and the dispensing pharmacist all agree that compounding this product is based on medical need is a step back. It does not seem wise to cut the prescribing physician out of the decision-making of patient care here, and we oppose this.	The Board agrees that a determination of a medical need by a medical provider is necessary. As the Board does not regulate prescribers, the requirement was removed from the proposed regulation text. The authorized healing arts board responsible for oversight of the prescriber would be responsible for evaluating for compliance with

				the medical need determination established in federal law.
9	1735.1(e)(1)	Novo Nordisk	We reiterate our request that the Board update Section 1735.1(e)(1) to state only the prohibition on compounding of "essentially a copy of one or more commercially available drug products," as defined at Section 17735(d), and to remove the exceptions to the copies restriction at (e)(1)(A) in the Third Modified Text related to shortage lists and inability of a health care facility to obtain a drug. In doing so, we ask that the Board reconsider the positions stated in the Staff Responses to NNI's comments to the Second Modified Text. As explained in NNI's prior comments, the exemptions in the proposed regulations from the copies prohibition are overly permissive and inconsistent with federal law and policy. The regulations 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.2 There, 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.3 The exemption that would permit compounding of copies when a drug product appears on the ASHP drug shortage list is clearly inconsistent with FDA's stated position – FDA has nowhere recognized that listing on the ASHP Drug Shortage list can permit compounding of copies; the agency has only stated as such with regard to FDA's drug shortage list. The proposed regulations are untenable in this respect, evidenced by the fact that the Staff Response to NNI's prior comments does not defend the reference to the ASHP list. Additionally, the proposed regulations would allow for compounding of copies when a health care facility "cannot obtain" a drug from the manufacturer or wholesaler. The Staff Responses point to a footnote in FDA's 503A Copies Guidance that states that the agency is considering the applicability of its policies described in the guidance to hospitals and health systems. Contrary to the staff's statement, FDA has promulgated draft guidance regarding application of the restriction on compounding copies to hospital and health	Board staff have reviewed the comment and do not recommend a change to the proposed text based on this comment. The Board has previously considered this comment and refers the commenter to the Board's prior response in row 9 available here that included in part, "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."

			system pharmacies.4 Therein, FDA states that "[i]n general, FDA intends to apply the policies described in the 503A copies guidance when it regulates compounding by hospital and health system pharmacies that are not registered as outsourcing facilities."5 While the agency does provide some flexibilities for such entities with regard to the prescriber determination requirement, FDA does not state any policy that would exempt these compounders from the copies restriction altogether based on the inability of the compounder to obtain a drug product from the manufacturer or wholesaler. Rather, FDA's policies regarding shortage stated in the 503A Copies Guidance would apply equally to hospitals and health systems. To best protect patient safety and the public health, and to avoid undermining a key check on compounding of unapproved drug products, we request removing, or at the very least narrowing, the broad permission for health care facilities to compound copies. Recommended language revision: "(e) In addition to prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, as defined at Section 1735(d) of this article. Documentation by the pharmacist that the compounded drug product produces a clinically significant difference for the medical need of an identified individual patient, as provided for at Section 1735(d) of this Article, must be maintained in a readily retrievable format."	
10	1735.1(e)(1)(a) and (c)	K. Scott Guess	How long must the documentation of drug shortage be retained?	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comment received. Board staff direct the commenter to proposed section 1735.14 to understand records requirements.
11	1735.1(e)(1)(A)	Obesity Action Coalition	We recommend that the Board update Section 1735.1(e)(1)(A) to align with FDA's interpretation of Section 503A that would only allow drugs to be compounded under certain circumstances. The proposed exceptions to the copies restriction at (e)(1)(A) in the Third Modified Text – are overly discretionary for healthcare facilities related to shortage lists and their inability to obtain a drug. The proposed Third	Board staff have reviewed the comment and do not recommend a change to the proposed text based on this comment. Board staff note that the proposed regulation text related to reference to the ASHP Drug Shortage List is consistent with current

			Modified Text, would further allow drugs to be compounded under circumstances when a drug product appears on the These broad exceptions are inconsistent with federal law and current policy and could perpetuate the manufacturing of illicit and unapproved compounded drug products when FDA-approved drugs are available to patients.	provisions with the law. The Board has received testimony from hospitals shortages that are not timely included on the FDA Drug Shortages Database. This testimony has included that the ASHP Drug Shortages List is another reliable source from drug shortage information. As part of the ASHP drug strategies for hospitals to ensure continuity of patient care. The FDA has stated its expectations that a manufacturer report discontinuation of or a supply interruption to and FDA approved drug. is not available, it can be helpful to make FDA's Drug Shortages staff aware. Usually when a drug is not in stock, it's a temporary, localized issue and more product is on the way. Occasionally local supply issues can be a signal of a future drug shortage. When FDA receives reports of new local shortages, we contact the manufacturers to confirm if their available supply will meet the national demand for the drug. If a drug is at risk of going into shortage, sometimes this advanced notice helps FDA take early action to prevent or shorten the duration of a shortage." It is the Board's understanding that such notifications and evaluation by the FDA may not be timely necessitating the need for an alternative source for assessing drug shortages that is more real-time.

12	1735.1(e)(1)(B)	CMA	CMA remains concerned that the Board's new proposed requirement for pharmacists to "verify" that a compounded drug produces a clinically significant difference for a patient creates an undue burden and restricts the professional judgment the Board intended to preserve. Mandating verification for every instance of compounding a commercially available drug that is not on a shortage list establishes a rigid, prescriptive standard. This contradicts the Board's stated goal of maintaining flexibility, and, as such, the language violates the clarity standard because it conflicts with the Board's description of the effect of the regulations in its formal response to members of the public regarding this issue. Pharmacists are already required to use their professional judgment in dispensing compounded drugs. 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. As written, the requirement could be interpreted to mean pharmacists must contact prescribers for verification in all cases where they compound a commercially available drug, leading to unnecessary delays in patient care. As a result, the lack of clarity within this requirement risks limiting access to necessary treatments, particularly in cases where compounded medications are essential alternatives to commercially available drugs. Federal law does not impose a verification or documentation requirement on pharmacists. Instead, the FDA, in non-binding guidance, recognizes documentation of a prescriber's determination as sufficient. The Board's proposal, by contrast, creates a new obligation without clear justification, increasing administrative complexity without improving patient safety.	Board staff note that the comment does address modification made in the third modified text. Board staff also note that the Board has previously considered the comment and determined that a change was not appropriate. Board staff refer the commenter to the Board's prior response to this comment from this commenter in row 10 available here that includes, "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: Health and Safety Code section 11153 Business and Professions Code section 733 Title 16, California Code of Regulations Section 1707.3"
13	1735.1(e)(2)	M. Cottman	**Recommendation:** Amend to remove the last sentence: ~~This compound shall be in compliance with the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022.~~ **Comments:** "Shall be in compliance with a [document]" This statement is far too non-specific as the GFI document contains Intro, Background, Paperwork Reduction Act and Appendices that link to websites. Specifically, what part of the 21 page GUIDANCE document SHALL we comply with? And what happens to 1735.1(e)(2) when the document changes or goes obsolete (yes the OMB has an expiration date on the document)? If you want additional required items that compounders should comply with for veterinary preparations, please don't make us hunt and peck for the language you are looking for, spell it out. Labeling? Documentation? Bulk Drugs for office use? Reporting ADEs to the FDA? What are you looking for???? It describes "The circumstances under which, at this time, FDA does not generally intend to take enforcement action against drugs compounded from bulk drugs substances for violations of the FD&C Act's requirements for approval, adequate directions for use, and CGMPs." The FDA states that it "generally does not intend to take enforcement action against" NINE (9) times in the document! GFI 256 is written as GUIDANCE, not as regulation nor law. It describes "The circumstances under which, at this time, FDA does not generally intend to take enforcement action against drugs compounded from bulk drugs substances for violations of the FD&C Act's requirements for approval, adequate directions for use, and CGMPs." Several items	Board staff have reviewed the comment and do not recommend any changes based on the comments. Board staff note that the comment does address modification made in the third modified text. Further, staff note that reference to the GFI included in 1735.1(e)(2) was made in response to commenters requesting that the language reference the document. Prior to recommending inclusion of the GFI, Board staff conferred with an expert on veterinary practice who confirmed incorporation of the document was appropriate.

			that are vague or open to interpretation. As well as statements that outright conflict with each other. Do compounders comply with the statement on pg 5 that: "drugs compounded from bulk drug substances violate the FD&C Act because they are not approved or indexed, are not made according to CGMP, and cannot satisfy the FD&C Act's adequate directions for use provision (which requires, among other things, that a prescription drug have FDA-approved labeling). " Or the statement also on pg 5: "[the] FDA recognizes that there are circumstances in which no FDA-approved or indexed drug (including the extralabel use of an FDA-approved animal or human drug) can be used to treat an animal with a particular condition. In those limited circumstances, an animal drug compounded from bulk drug substances may be a medically appropriate treatment. " Do we, as licensees assume that we should replace BOP wherever we see FDA in the document such as "This guidance describes: • The types of drugs compounded from bulk drug substances that FDA[BOP] has determined present the greatest risk to human and animal health and intends to make priorities for enforcement action; and • The circumstances under which, at this time, FDA [BOP[does not generally intend to take enforcement action against drugs compounded from bulk drugs substances…"	
14	1735.1(f)	M. Cottman	**Recommendation:** Remove this section. ~~(f) Prior to allowing any CNSP to be compounded within a pharmacy, the pharmacist-in-charge shall complete a self-assessment consistent with the requirements established in section 1715.~~ **Comments:** Redundant. This is not making a new rule, it is just reminding compounders to follow existing regulation 1715 to complete a self-assessment. To comply with 1715, a PIC must fill out the form before July 1 of every odd numbered year…	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Board staff note that the comment does address modification made in the third modified text. Board staff note that section 1715 does not establish a requirement to complete the self-assessment specifically related to compounding.

			What is it that you want done differently? We are already so highly regulated! Wasting text on re-stating existing laws doesn't help clarify anything. Further, a more appropriate approach would be to create a separate rule making process to address adding the Compounding Self Assessment requirement to section 1715, in line with all the other references to Self Assessments since CCR 1735.2[k] will be repealed if this text is adopted.	
15	1735.1(g)	M. Cottman	(1) directions for use and storage and the importance of compliance with directions;" Restating these items here does not clarify anything.	Board staff have reviewed the comment and do not recommend changes based on the comment received. As was discussed previously by the Board, the provisions in CCR 1707.2 do not include requirements related to handling and disposal nor do they require consultation on provisions for related supplies furnished.
16	1735.1(i)	CVS	CVS Health greatly appreciates the collaboration that has led to numerous changes in pending language throughout this promulgation, including 1735.15(b), which allows flavoring without a patient specific prescription. However, the language and methodology used to craft 1735.1(i) and 1735.15(a), which create two pathways for flavoring compliance, causes confusion and is not clear to the regulated community. The first pathway is to follow USP Chapter 795, FDCA section 503a, 1735.1 through 1735.14, and 1735.15(b), which I'll refer to as "pathway A". The second pathway is to follow 1735.14, 1735.15, USP Chapter 795, and FDCA section 503a, however a pharmacy cannot otherwise engage in nonsterile compounding in order to utilize this pathway, which I'll refer to as "pathway B". Although pathway B has been billed as an exception, CVS Health believes that pathway B arguably establishes a greater mandate than just adhering to pathway A, as 1735.15(a)(5) requires a labeling mandate when flavoring while 1735.5 does not. Otherwise, 1735.1 through 1735.14 largely reiterate USP Chapter 795, and as 1735.15 also requires adherence to USP	Board staff have reviewed the comments and do not recommend a change to the proposed text. The Board cannot waive provisions of federal law. The Board can provide clarity to the requirements. The Board's proposal related to flavoring allows for maximum flexibility for a pharmacy to operationalize the requirements when a pharmacy adds a flavoring agent. The Board reminds the commenter about provisions in exist law related to maintaining facilities found in 16 CCR Section 1714 which states in part that "a pharmacy shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed." This section further provides that "the pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition." Board staff believe that a pharmacy that is compliant with the provisions in 1714 should

			Chapter 795, it is questionable why pathway B exists. Pathway B would truly be an exception, if adherence to USP 795 was struck from 1735.15(a), as requested below. Since it is unlikely community pharmacies will ease offering patients non-sterile compounding services in lieu of flavoring services exclusively, pathway B is not an option. Community pharmacies are simply highly unlikely to engage in flavoring if adherence to USP Chapter 795 is required. While there are several portions of USP Chapter 795 that we believe are too onerous without benefit to public safety to be applied to the act of flavoring a prescription, I'll offer one example. USP Chapter 795 requires gloves to be worn and the cleaning and sanitizing of the surfaces in the nonsterile compounding area on a regular basis or as specified in the USP. CVS Health's request: pathway B not be tied to abstaining from engaging in nonsterile compounding and for pathway B to not require adherence with USP Chapter 795, as depicted below. Otherwise, community pharmacies will likely not be able to offer California patients flavoring, which deviates from the overwhelming majority of other states. (i) A facility that ~~limits its compounding to~~ combin~~es~~ing 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.~~	also be compliant with the USP 795 Chapter when flavoring.
17	1735.1(i)	FLAVORx	If the intention of the Board is to bring medication flavoring back to California's pharmacies and families, which you've indicated it is, then the language you are considering for approval will not accomplish that. The caveat language in 1735.1 (i), which ties the regulation of flavoring to other pharmacy activities, is the problem. Tethering flavoring to totally unrelated products or services offered in the pharmacy will prevent pharmacies from reintroducing the service.	Board staff have reviewed the comment. Board staff have reviewed the comment and believe the language is clear. Board staff note that federal law and national standards establish the combining of a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form as compounding. Staff note that the FDA and

			Why is the sole act of flavoring FDA approved liquid medications being tied to other, totally unrelated activities in the pharmacy? What does producing a Magic Mouthwash solution for a chemotherapy patient have to do with flavoring an amoxicillin prescription for a child with strep throat? Why can't pharmacies that choose to flavor just abide by the provisions in 1735.15 and leave it at that? The Board itself appears confused and confounded by this language as well, as evidenced by comments from Member Sandhu at the January 8 meeting and Chair Oh and Member Crowley at the February 5 meeting. **The practical implication of approving the language as is will be to perpetuate the freeze on pharmacies offering flavoring to their customers**. The pharmacies I've spoken with would like to start flavoring again AND continue to provide basic non-sterile compounding to their customers. But these same pharmacies have indicated clearly, in both their words and actions, that they cannot and will not have flavoring regulated the same as, for example, preparing Magic Mouthwash. You are forcing this language, which is not in any way beneficial to consumers. If the Board is OK with the exemptions for flavoring that are provided in 1735.15, then it should be OK with them in all cases, independent of what other services the pharmacy provides. Here's the easy fix: **"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."** Plain. Simple. No caveats. You have made great progress with the exemptions contained in 1735.15. Please don't make it all for naught.	The Board's approach is to establish maximum Board staff also note that the provisions related to flavoring have been amended significantly since the formal rulemaking began in response to public comments. In the original version of not include any exemptions to the Board's regulation requirements.
18	1735.2(c)	K. Scott Guess	How long must this documentation be retained?	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comment received. Board staff direct the commenter to proposed section 1735.14 to understand records requirements.
19	1735.4(b)	K. Scott Guess	Please define "high quality water". Is any municipal water supply high quality?	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment

				received. Board staff note that the comment does address modification made in the third modified text. Staff also note that the commenter is not accurately reflecting the proposed text, which reads "Purified water, distilled water, reverse osmosis water, or **higher** quality water shall be used for rinsing equipment and utensils." Staff further note that the Board previously considered a comment related to water quality and noted the following "Staff note that USP identifies various grades of water including in Section 4.3 of the Chapter. Staff notes that the quality of water is of significance for patient safety."
20	1735.5(a)	K. Scott Guess	The cleaning and sanitizing supplies used are stated in the Policy and Procedure manual. It is unnecessary to record this information daily and only adds to costs without adding to patient safety.	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment received. Board staff note that the comment does address modification made in the third modified text. Board staff note that the Board previously considered similar comments on this issue and provided the following response, "Staff believe that documentation of the cleaning process as described in the proposed language is appropriate and consistent with the actions necessary to maintain and clean compounding environment. Staff note that operationalizing the requirements could be quite simple, including a prepared log that already has the items listed…"
21	1735.6(a)	K. Scott Guess	Compounding is an art form. Techniques, tools, and equipment are subject to being used in new and unique ways to achieve a product that a patient can use/tolerate. From a patient outcomes view, restricting equipment use to manufactures specifications inhibits innovation that can result in good patient outcomes. It is my opinion this section should	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment received. Board staff note that the comment does address modification made in the third modified text.

			be eliminated. The sole purpose of compounding is to adopt existing drugs to a specific patients' needs.	Further, Board staff note that it is not appropriate to use equipment for other than its intended purpose and that doing so could compromise public safety. As an example, using a food grade blender for chemicals could result in leaching into the compounded preparation.
22	1735.8(a)	K. Scott Guess	Including the dispensing pharmacist as being responsible for the integrity, strength, quality, and labeled strength places undue liability on the dispensing pharmacist who may not have been on duty when the CNSP was compounded; therefor has no process other than the compounding record to base that decision on; a compounding record that was already checked and approved by another licensed pharmacist. The "dispensing pharmacist" should be eliminated, and limited to the pharmacist that made, or signed off on the compound.	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment received. Board staff note that the comment does address modification made in the third modified text. Board staff note that, in response to a comment received during 45-day comment period, the proposed modified text was modified to include the dispensing pharmacist. Staff note that the language in the proposed text incorporates a change requested by prior comment received in response to the 45-day comment period. That commenter suggested, the dispensing pharmacist is responsible for the patient label. The Board agreed and previously accepted the change requested.
23	1735.10(b)(2)	M. Cottman	**Recommendation:** Remove this section. If you won't remove it, then please consider a 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.* **Comment:** USP already addresses what to consider when determining BUDs. I ***repeat*** my previous concerns! It is not clear who has the burden of proof that the CNSP is reactive or non-reactive with the container- closure system. This data is rarely readily available (compounder or Board)! Amber bottles, ointment jars, and oral syringe container closures are standard in the field of compounding, but where are the studies for the hundreds of APIs that we use to solve unique patient issues? And again, the testing to provide proof of compatibility is	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment received. Board staff note that the comment does address modification made in the third modified text. Further, board staff note that USP 795 specifies that "a compounder **MUST** consider parameters that may affect quality, including but not limited to the following…compatibility of the container closure system with the finished preparation (e.g., leachables, interactions, …)" The Board's reference to the

			many $1,000s! Under this proposed rule, when a prescriber identifies 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 compounds for patients with unique needs!*	container closure provisions in this section referenced by the commenter is consistent with the provisions of the chapter.
24	1735.11(a)(2), 1735.12(b) & (c)	Partnership For Safe Medicines	The Board's proposal to eliminate adverse event reporting requirements (sections 1735.11(a)(2), 1735.12(b), 1735.12(c), and 1736.17(a)(2)) presents severe risks, including: ● Delayed Detection of Drug Safety Issues: Without a diminished reporting system, it will take longer to identify harmful trends associated with specific medications. ● Reduced Transparency: Patients and healthcare providers will have less access to critical safety data that inform medical decision-making. ● Increased Harm from Compounded Medications: The absence of adverse event reporting will make it harder to promptly identify and respond to dangerous medications before widespread harm occurs. A Step Backward in Drug Safety California has historically been a leader in pharmaceutical regulation and patient protection. Removing adverse drug experience review would reverse this progress, making the state an outlier in drug safety oversight. Regulatory bodies, including the FDA and WHO, emphasize the necessity of adverse event monitoring as a fundamental component of a responsible healthcare system. The California Board Of Pharmacy should reject this proposed rule change and reiterate the responsibilities of compounders to have a standard operating procedure that requires mandatory reporting of all adverse events promptly.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on the comment received. Board staff note that the comment does address modification made in the third modified text. The Board's proposed compounding regulations are seeking to establish minimum requirements while relying on pharmacists to use their professional judgment. Staff note that the Board, as part of its January 8, 2025, meeting, and in response to public comment, the Board determined that removal of the requirement for a pharmacist to review all adverse drug experiences for nonsterile preparations was not necessary to be included in the proposed regulation text but would be a best practice for pharmacists to evaluate for trends with product quality issues where unexpected adverse drug experiences are reported. Staff note that during its discussion, the Board noted that such action is not required under federal law. Staff further note that the commenter included reference to the compounding of GLP-1s, which are sterile compounding preparations. The requirements for sterile compounding preparations are included in Article 4.6.

25	1735.11 and 1735.12	Obesity Action Coalition	Compounded drugs lack the same level of safety, efficacy, and quality assurances of FDA-approved drugs, and compound facilities and pharmacies lack adequate systems for tracking and tracing and reporting adverse events associated with their drugs. OAC strongly recommends reinserting all references to "adverse drug experiences" to ensure that compounding facilities are required to notify the Board of adverse events involving compounded products. As you know, compounding pharmacies are not required to do surveillance, evaluation, or reporting of adverse events to FDA. It is unacceptable to put the onus on the patient who purchases a compounded drug from a retail pharmacy to report adverse events to the outsourcing compounding facility. How could they, given they have no knowledge or direct connection? The risk of missed adverse events is amplified when compounding facilities partner with telehealth companies and other online vendors that do not conduct adverse event reporting. Requiring adverse event reporting and limiting distribution to products strengthens safety, control of the process, and communication to patients.	Board staff have reviewed the comment and do not recommend changes to the proposed regulation text based on the comment received. Board staff note that the comment does address modification made in the third modified text. Board staff agree with the commenters concerns about patient safety and potential risks from compounded preparation. The Board's proposed compounding regulations are seeking to establish minimum requirements while relying on pharmacists to use their professional judgment. Staff note that the Board, as part of its January 8, 2025, meeting, and in response to public comment, the Board determined that removal of the requirement for a pharmacist to review all adverse drug experiences for nonsterile preparations was not necessary to be included in the proposed regulation text but would be a best practice for pharmacists to evaluate for trends with product quality issues where unexpected adverse drug experiences are reported. Staff note that during its discussion, the Board noted that such action is not required under federal law. Staff further note that the commenter included reference to the compounding of GLP-1s, which are sterile compounding preparations. The requirements for sterile compounding preparations are included in Article 4.6.
26	1735.12(b)	K. Scott Guess	The Board is asking to be inundated with unnecessary paperwork to evaluate. There are many reasons a patient might complain about a compounded product: flavor, texture, dosage form preference, etc. ONLY VALIDATED complaints regarding integrity, strength, and quality should be reported to the board. The board does not to spend time and money investigating complaints of flavors, or texture, or even a	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 comment does address modification made in the third modified text.

			complaint about strength IF the pharmacy sends the product in question for testing and the product results are within specifications. Respectfully, the board made this mistake already with the reporting ANY loss of controlled substance found during the controlled substances reconciliation.	Board staff note that nonresident pharmacies are currently required to report such complaints. The proposed regulation text will create parity in reporting for resident pharmacies and provide the Board with the opportunity to evaluate the issue and where necessary conduct an investigation.
27	1735.12(b)	CSHP	The way that this regulation is worded could be misinterpreted. This proposed regulation was discussed by the board during the last board meeting, and it was mentioned that the intent is for complaints that indicate true quality problems be reported to the board. From the way that it is written, the understanding that one could derive from the language is that the board must be notified of all complaints that could potentially indicate a quality problem. For example, a patient given a compounded gel, could complain that from their recollection it appears to have a slightly different opacity from one dispensed previously. Since this could potentially indicate a quality problem, the pharmacist will then report the complaint of a potential quality problem to the board. The pharmacist then investigates and finds that the medication was compounded correctly but the master formula was changed to a different gel base due to a change in manufacturers. One of members reported to CSHP that they started to report all complaints that could indicate a potential complaint to the board. They were instructed by board staff that they should only report it when there was an actual quality problem since they were inundating the board with reports. It shows that there has been confusion with the current regulations. It is important that we use this opportunity to make the language as clear as possible. While all involved currently in the creation and comments may have a grasp and understanding of the intent of this proposed regulation, we must take the multiple comments from all stakeholders as an indicator that there will be future misunderstanding and misinterpretations of this language. It is of the utmost importance to recognize that ten to fifteen years from now these interpretations and intent will be forgotten, and the only guidance left to enforce are the words as written. We are sure that the current board would not want future board members and staff to enforce this rule under the	Board staff have reviewed the comment and do not recommend a change in the proposed text based on the comment. Board staff note that the comment does address modification made in the third modified text. Board staff do not share concerns suggested by the commenter about potential overreporting and potential workload impact to Board staff. The proposed regulation text will create parity in reporting for resident pharmacies and provide the Board with the opportunity to evaluate the issue and where necessary conduct an investigation.

			misunderstandings that we and others took great pains to point out at this moment in time. Recommendation: (b) The pharmacy shall report in writing a product quality issue for any compounded product to the board within 96 hours after the pharmacy receives notice of the product quality issue.	
28	1735.12(b)	M. Cottman	**Recommendation:** Amend to clarify. The Board shall be notified in writing within 96 hours of the facility's receipt of a complaint ~~of a~~ determined to be a potential quality problem involving a CNSP. **Comments:** Clarifying this wording will prevent unnecessary communications with the Board about complaints NOT related to a compounding ***quality*** issue.	Board staff have reviewed the comment and do not believe a change to the proposed regulation text is necessary. Staff note that the Board's policy and the proposed regulation text are clear. A PIC is responsible for evaluating the issue consistent with the facility's SOPs. The PIC's evaluation and conclusion will determine if the Board is required to be notified.
29	1735.13	M. Cottman	Recommendation: Remove Comments: This statement does not provide anything in addition to USP 795 quoted here: 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."	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Board staff note that the comment does address modification made in the third modified text. This comment was previously considered by the Board. The Board respectfully refers the commenter to its prior response in row 25 available here that includes "**The proposed regulation text ensures the facility establishes specific SOPs for storage, shipping containers and temperature sensitive CNSPs.**"
30	1735.15(a)	CVS	CVS Health greatly appreciates the collaboration that has led to numerous changes in pending language throughout this promulgation, including 1735.15(b), which allows flavoring without a patient specific prescription. However, the language and methodology used to craft 1735.1(i) and 1735.15(a), which create two pathways for flavoring compliance, causes confusion and is not clear to the regulated community. The first pathway is to follow USP Chapter 795, FDCA section 503a, 1735.1 through 1735.14, and 1735.15(b), which I'll refer to as "pathway A". The second pathway is to follow 1735.14,	Board staff have reviewed the comment and do not recommend any changes to the proposed text. It appears the commenter is suggesting that the Board promulgate regulations contrary to federal law and national standards. The Board's proposed regulation text provides maximum flexibility for facilities to meet the requirements of the national standards. As cited elsewhere in the requirements, facilities are required to meet operational conditions including for example

			1735.15, USP Chapter 795, and FDCA section 503a, however a pharmacy cannot otherwise engage in nonsterile compounding in order to utilize this pathway, which I'll refer to as "pathway B". Although pathway B has been billed as an exception, CVS Health believes that pathway B arguably establishes a greater mandate than just adhering to pathway A, as 1735.15(a)(5) requires a labeling mandate when flavoring while 1735.5 does not. Otherwise, 1735.1 through 1735.14 largely reiterate USP Chapter 795, and as 1735.15 also requires adherence to USP Chapter 795, it is questionable why pathway B exists. Pathway B would truly be an exception, if adherence to USP 795 was struck from 1735.15(a), as requested below. Since it is unlikely community pharmacies will ease offering patients non-sterile compounding services in lieu of flavoring services exclusively, pathway B is not an option. Community pharmacies are simply highly unlikely to engage in flavoring if adherence to USP Chapter 795 is required. While there are several portions of USP Chapter 795 that we believe are too onerous without benefit to public safety to be applied to the act of flavoring a prescription, I'll offer one example. USP Chapter 795 requires gloves to be worn and the cleaning and sanitizing of the surfaces in the nonsterile compounding area on a regular basis or as specified in the USP. CVS Health's request: pathway B not be tied to abstaining from engaging in nonsterile compounding and for pathway B to not require adherence with USP Chapter 795, as depicted below. Otherwise, community pharmacies will likely not be able to offer California patients flavoring, which deviates from the overwhelming majority of other states. (a) ~~In addition to the standards in USP Chapter 795 and the Food Drug Cosmetic Act (FDCA) section 503a (21U.S.C. 353a) a~~ A facility that ~~limits its compounding~~ flavors as described in Section 1735.1(i) shall establish the following SOPs:	maintaining facilities as established in CCR 1714.