#	Section	Commenter	Comment	Staff Response
1	1735(d)	CA Medical Association	**Requirement to Verify a Preparation Produces a Clinically Significant Difference Interferes with Exercise of Professional Judgment and Exceeds Federal Law (§§ 1735(d), 1735.1(e)(1)(B), 1736(d), 1736.1(e)(1)(B))** CMA reiterates its concern regarding the Board's proposed requirement for pharmacists to "verify" that a compounded drug produces a clinically significant difference for a patient. This proposed requirement creates an undue burden and restricts the professional judgment the Board intended to preserve. Mandating verification for every instance of compounding a commercially available drug that is not on a shortage list establishes a rigid, prescriptive standard. This contradicts the Board's stated goal of maintaining flexibility, and, as such, the language violates the clarity standard because it conflicts with the Board's description of the effect of the regulations in its formal response to members of the public regarding this issue.8 We refer you to our comment letters dated January 27 and February 21, 2025, for detailed discussions of this issue. To enhance clarity and ensure patients maintain timely access to medications, CMA reiterates its request from our prior comment letter, dated January 27, 2025, to remove "verify and" from proposed sections 1735(d), 1735.1(e)(1)(B), 1736(d), and 1736.1(e)(1)(B) of the third modified text.	Board staff have reviewed the comment and do not recommend a change in the proposed text. Board staff note that the comment is outside the scope of the proposed changes in the fourth modified text. The Board has previously considered these comments. The Board respectfully refers the commenter to the Board's prior responses.
2	1735(d)	Wedgewood	Please clarify that this language applies to compounds intended for human patients. Guidance For Industry 256 provides a different definition of "Essentially a Copy" as it pertains to veterinary medicine that includes route of administration as a factor for consideration. Please consider the addition of language to align this definition with the federal standard as it relates to animal medicine. We do not recommend a direct reference to GFI 256 for the reasons outlined below (1735.1(e)(2)).	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 comment is outside the scope of the proposed changes in the fourth modified text. Further, this comment has been previously considered by the Board. The Board respectfully refers the commenter to the Board's prior response. In addition to the Board's prior comments, the Board highlights that it's essentially a copy definition relies heavily on a pharmacist's

				professional judgement in making a determination if a compounded preparation would provide a clinically significant difference for the patient, which would include an animal patient.
3	1735(d)	CSHP	We once more emphasize that us and others who commented on this section remain concerned with the wording of this section. We appreciate the board's position that the intent is to rely on the professional judgement of the pharmacist. At the same time, we object to the wording of the regulation and wish to point out that this section has the potential to be misinterpreted as written, both currently and in the future. It is important to get this right so that the intent is clear and does not cause confusion. The wording of ""Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product," could be interpreted to mean that ANY compound being made is defined as essentially a copy of a commercially available drug product. The trouble here is that any compounded drug that has the same API as a commercially available drug product will violate this regulation. Using the example of a hospital pharmacy that compounds a batch of 20 doses of "GI Cocktail" for use in the Emergency Department. To make this compound, the pharmacy mixes together Donnatal®, Viscous Lidocaine and an antacid such as Maalox®. By the definition above copied from the proposed regulation, it will be a violation of this proposed regulation since these doses are compounded and will be seen as including the same API as the commercially available products from which they are compounded. To further explain, since the compounded product contains lidocaine, it violates the proposed regulation since it contains the same API (lidocaine as the commercially available viscous lidocaine. Additionally, since the compounded product contains Donnatal®, it violates the proposed regulation since it contains the same API as the commercially available Donnatal®. Additionally, since the compounded product contains Maalox®, it violates the proposed regulation since it contains the same API as the	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 comment is outside the scope of the proposed changes in the fourth modified text. Further, this comment has been previously considered by the Board. The Board respectfully refers the commenter to the Board's prior response. In addition to the Board's prior comments, the Board highlights that it's essentially a copy definition relies heavily on a pharmacist's professional judgement in making a determination if a compounded preparation would provide a clinically significant difference for the patient. There is nothing in the proposed regulation text that would prevent the batch compounding process described in the comment from occurring. Rather, the proposed regulations would provide that prior to administration of the compounded product, a pharmacist, using their professional judgement, has made a determination that the compounded product is appropriate and produces a clinically significant difference for the patient.

			commercially available Maalox®. These products are being used routinely in the ER for abdominal conditions. This proposed regulation, if it is read simply for the way it is stated, will imply that the pharmacist verifying the order will need to go through a process of verifying with the prescriber and then documenting each and every order for GI Cocktail that the change from the 3 commercially available products to a compounded GI Cocktail produces a clinically significant difference for each individual patient. This unintended consequence of altering the work of pharmacists and physicians in the ER was not explained in the ISOR. We are deeply concerned that the language as written, will cause additional communication and documentation of the communications for both physicians and pharmacists. We are concerned that board staff's previous response to this concern did not demonstrate their understanding of our concern. In the ISOR, the board states that the FDA guidance document is being utilized to provide guidance regarding this definition: It is important to note that the definition taken from the FDA guidance document and used in this proposed regulation, is only one part of three of the definition in the guidance document. Herewith the guidance document section on "Essentially a Copy" for reference: FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if: • the compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product; • the API(s) have the same, similar, or an easily substitutable dosage strength; and • the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug, unless, as provided by section 503A(b)(2), a prescriber determines that there is a change, made for an identified individual patient, which produces, for that patient, a	

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

			importance to recognize that ten to fifteen years from now these interpretations and intent will be forgotten, and the only guidance left to enforce are the words as written. We are sure that the current board would not want future board members and staff to enforce this rule under the misunderstandings that we and others took great pains to point out **at this moment in** time. We are concerned that Board staff's previous response to this concern did not demonstrate their understanding of our concern. **Recommendation:** (d) "Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product, **the API(s) have the same, similar, or an easily substitutable dosage strength; and the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug** except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as **verified and documented** by the **pharmacist**, between that compounded preparation and the comparable commercially available drug product.	
4	1735.1	FLAVORx	As you know from my previous comments, the language is a dealbreaker for pharmacies since it ties flavoring regs to other activities a pharmacy may need to perform. I realize that previous suggested fixes to the language created a potential loophole where pharmacies could argue they would be exempt from the new, modified non-sterile compounding requirements for practices unrelated to flavoring. That was not our intention, and I apologize if it came across as such. We are only concerned with flavoring. As you'll see from the suggested edits to the text below, you can avoid all confusion by focusing solely on the act of flavoring, instead of the facility that performs it. The language I'm proposing allows flavoring to stand alone, independent of other activities performed in the pharmacy, making it highly likely you will achieve the goal of getting flavoring back in California's pharmacies.	Board staff have reviewed the comment and do not recommend a change in the proposed text. Board staff note that the comment is outside the scope of the proposed changes in the fourth modified text. Board staff note that the recommended text could create confusion regarding the requirement for pharmacies that engage in nonsterile compounding. The Board's proposed regulation text is appropriate and provides clarity on the requirements.

			The issue is the mention of "facility" so let's focus on the "act" instead. Here's an easy fix that ensures the exemptions only apply to flavoring medications: (i) ~~A facility that limits its compounding to~~ the sole act of combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of a prescriber, patient, or patient's agent shall be exempt from the requirements established in subdivision (f) and Sections 1735.2 – 1735.13. ~~A facility that performs any other form of nonsterile compounding at any time is not exempt as provided in this subdivision.~~ The performance of any other form of nonsterile compounding is not exempt from the requirements established in subdivision (f) and Sections 1735.2-1735.13.	
5	1735.1(e)(1)	Novo Nordisk	**Comment:** We reiterate our request that the Board update Section 1735.1(e)(1) to state only the prohibition on compounding of "essentially a copy of one or more commercially available drug products," as defined at Section 1735(d), and to remove the exceptions to the copies restriction at (e)(1)(A) related to shortage lists and inability of a health care facility to obtain a drug. As explained in NNI's comments on the Second and Third Modified Texts, the provisions relating to the ASHP Drug Shortage List and compounding when a health care facility cannot obtain a drug from the manufacturer or wholesaler are inconsistent with federal law and policy. These broad permissions for compounding copies create risks for patient safety and the public health, and undermine a key check on compounding of unapproved drug products. **Recommended language revision:** "(e) In addition to prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, as defined at Section 1735(d) of this article. Documentation by the pharmacist that the compounded drug product produces a clinically significant difference for the medical need of an identified individual patient, as	Board staff have reviewed the comment and do not recommend a change in the proposed text. Board staff note that the comment is outside the scope of the proposed changes in the fourth modified text. The Board has previously responded to similar comments from this commenter and the Board respectfully refers the commenter to this Board's prior response. Further, the Board notes that it is seeking to align with federal law and federal guidance. The Board continues to monitor for information from the FDA related. Licensees of the Board are required to maintain a strong understanding of federal law and guidance documents released. It is the Board's expectation that pharmacists, using professional judgment, will make appropriate decisions for patients consistent with their education training and consistent with all legal requirements and with the standard of care.

			provided for at Section 1735(d) of this Article, must be maintained in a readily retrievable format."	
6	1735.1(e)(1)(B)	CA Medical Association	**Requirement to Verify a Preparation Produces a Clinically Significant Difference Interferes with Exercise of Professional Judgment and Exceeds Federal Law (§§ 1735(d), 1735.1(e)(1)(B), 1736(d), 1736.1(e)(1)(B))** CMA reiterates its concern regarding the Board's proposed requirement for pharmacists to "verify" that a compounded drug produces a clinically significant difference for a patient. This proposed requirement creates an undue burden and restricts the professional judgment the Board intended to preserve. Mandating verification for every instance of compounding a commercially available drug that is not on a shortage list establishes a rigid, prescriptive standard. This contradicts the Board's stated goal of maintaining flexibility, and, as such, the language violates the clarity standard because it conflicts with the Board's description of the effect of the regulations in its formal response to members of the public regarding this issue.8 We refer you to our comment letters dated January 27 and February 21, 2025, for detailed discussions of this issue. To enhance clarity and ensure patients maintain timely access to medications, CMA reiterates its request from our prior comment letter, dated January 27, 2025, to remove "verify and" from proposed sections 1735(d), 1735.1(e)(1)(B), 1736(d), and 1736.1(e)(1)(B) of the third modified text.	Board staff have reviewed the comment and do not recommend a change in the proposed text. Board staff note that the comment is outside the scope of the proposed changes in the fourth modified text. The Board has previously considered these comments. The Board respectfully refers the commenter to the Board's prior responses.
7	1735.1(e)(2)	Wedgewood	We appreciate that the Board addressed our earlier concerns about the ambiguous reference to AMDUCA, but we continue to remain concerned about a direct reference to a Guidance Document that could be eliminated tomorrow by the current administration. What will compliance look like if the Agency rescinds or edits the guidance document making this reference irrelevant? We again make the following Recommendation: This compound shall be in compliance with current industry guidance. the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022.	Board staff have reviewed the comment and do not recommend a change in the proposed text. Board staff note that the comment is outside the scope of the proposed changes in the fourth modified text. The Board has previously considered these comments. The Board respectfully refers the commenter to the Board's prior responses.
8	1735.12(b)	CSHP	We are concerned that board staff's comments regarding our concern does not reflect the intent that board members	Board staff have reviewed the comment and do not recommend a change to the

			verbalized during the full board meeting. We therefore request that board members review our concerns and indicate their agreement or disagreement with staff's response. We once more reiterate our previous concerns. The way that this regulation is worded could be misinterpreted. This proposed regulation was discussed by the board during the last board meeting, and it was mentioned that the intent is for complaints that indicate true quality problems be reported to the board. From the way that it is written, the understanding that one could derive from the language is that the board must be notified of all complaints that could potentially indicate a quality problem. For example, a patient given a compounded gel, could complain that from their recollection it appears to have a slightly different opacity from one dispensed previously. Since this could potentially indicate a quality problem, the pharmacist will then report the complaint of a potential quality problem to the board. The pharmacist then investigates and finds that the medication was compounded correctly but the master formula was changed to a different gel base due to a change in manufacturers. One of our members reported to CSHP that they started to report all complaints that could indicate a potential complaint to the board. They were instructed by board staff that they should only report it when there was an actual quality problem since they were inundating the board with reports. It shows that there has been confusion with the current regulations. It is important that we use this opportunity to make the language as clear as possible. We are concerned that Board staff's previous response to this concern did not demonstrate their understanding of our concern and did not explain why board staff instructed the health system to stop reporting all potential quality problems. While all involved currently in the creation and comments may have a grasp and understanding of the intent of this proposed regulation, we must take the multiple comments from all stakeholders as an indicator that there will be future misunderstanding and misinterpretations of this language. It is of the utmost importance to recognize that ten to fifteen years from now these interpretations and intent will be forgotten, and the only guidance left to enforce are the words as written.	proposed text based on the comment received. Board staff note that the comment is outside the scope of the proposed changes in the fourth modified text. Board staff respectfully refer the commenter to prior responses that have been approved by the Board. Further, the Board notes that a pharmacist, using their professional judgment would determine if reporting of a potential quality problem is necessary. The pharmacist, understanding the specific facts of potential quality problem is best suited to make such a determination. As the Board seeks to transition to a more robust standard of care model, where pharmacists believe additional clarity is required, a pharmacist can include in standard operating procedures criteria if determined appropriate.

			We are sure that the current board would not want future board members and staff to enforce this rule under the misunderstandings that we and others took great pains to point out at this moment in time. Recommendation: (b) The pharmacy shall report in writing a product quality issue for any compounded product to the board within 96 hours after the pharmacy receives notice of the product quality issue.	
9	1735.15	FLAVORx	For the same reasons stated above, this language will prevent pharmacies from flavoring medications. The fix is the same. Focus on the "act' and not the "facility". Here is what we suggest: (a) In addition to the standards in USP Chapter 795 and section 503a (21 U.S.C. §353a) the of the Federal Food, Drug, and Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) ~~a facility that limits its compounding as described in Section 1735.1(i) shall establish the following SOPs:~~ facilities shall establish the following SOPs for the sole act of combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form:	Board staff have reviewed the comment and do not recommend a change in the proposed text. Board staff note that the comment is outside the scope of the proposed changes in the fourth modified text. Board staff note that the recommended text would create confusion and conflict with the article governing nonsterile compounding.