#	Section	Commenter	Comment	Staff Response
1	1736	Marie Cottman	**Recommend removing duplicate language.** The definitions in this section shall be applicable to this Article and supplement the definitions provided in United States Pharmacopeia (USP) General Chapter 797 (USP Chapter 797), titled Pharmaceutical Compounding – Sterile Preparations. ~~The following definitions apply to this article and supplement the definitions provided in USP Chapter 797 for compounded sterile preparations (CSPs).~~	Board staff have reviewed the comment and thank the commentator for pointing out that duplication resulted from multiple rewrites. Staff offers the following changes: **1736. Sterile Compounding Definitions.** The definitions in ~~**in**~~ this section shall be applicable to this Article and supplement the definitions provided in United States Pharmacopeia (USP) General Chapter 797 (USP Chapter 797), titled *Pharmaceutical Compounding – Sterile Preparations*~~. The following definitions apply to this article and supplement the definitions provided in USP Chapter 797~~ for compounded sterile preparations (CSPs).
2	1736(d)	CMA	CMA is concerned that the Board's proposed modified text establishes a new requirement for pharmacists to "verify" that a prescribed compounded drug product produces a clinically significant difference for the medical need of an identified individual patient under specific conditions. CMA acknowledges the role of pharmacists exercising professional judgment, as outlined in Business and Professions Code (BPC) section 4306.5. However, the proposed requirement to "verify" introduces unnecessary and unintended rigidity into the process. Contrary to the Board's assertion, mandating verification in every instance of compounding a drug that is otherwise commercially available and not on a shortage list sets a prescriptive standard for how pharmacists must exercise their professional judgment. The language of the regulations expressly requires pharmacists to verify the existence of a clinically significant difference for each compounded preparation in this	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 was amended to require a pharmacist to verify that a prescribed medication is clinically appropriate for a patient, irrespective of whether it is a compounding 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 and BPC 733.

#	Section	Commenter	Comment	Staff Response
			situation, rather than allowing pharmacists to exercise their professional judgment as to when such verification may be warranted. This mandate impedes the flexibility the Board claims to seek to preserve and, as such, the language violates the clarity standard because it conflicts with the Board's description of the effect of the regulations in its response above. Pharmacists are already obligated to exercise judgment when dispensing dangerous drugs and are empowered by BPC section 733(b)(1) to refuse to dispense a prescription based on professional judgment, potential harm, or legal concerns. Eliminating the "verify" requirement from the proposed regulation would not abrogate pharmacists' statutory responsibilities but would instead maintain the flexibility pharmacists need to practice most effectively. The verification requirement would also impose significant administrative burdens on both pharmacists and prescribing physicians. For each compounded medication, pharmacists would need to collect and document proof of verified clinical significance for the prescribed drug, while physicians may be required to provide additional supporting evidence. This process could lead to delays in dispensing compounded medications, creating barriers for patients who rely on these treatments. For some patients, such delays could limit timely access to necessary therapies, ultimately harming their care. Finally, federal law, specifically 21 USC § 353a and 21 CFR Part 216, does not establish a documentation requirement, let alone a verification requirement for compounding. FDA guidance only recommends that "[…] the compounder should ensure that the determination is documented on the	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 Title 16, California Code of Regulations Section 1707.3

#	Section	Commenter	Comment	Staff Response
			prescription." The guidance also clarifies that the FDA "[…] generally does not intend to question prescriber determinations that are documented in a prescription or notation." Current state regulations require pharmacists to retain the documentation of the determination of clinical significance. The Board's proposal, however, goes beyond all of these standards by mandating that pharmacists both verify and document the prescriber's determination. This additional verification obligation introduces a new requirement, not a clarification of existing state or federal statute. By creating this new regulatory standard, the proposal could be interpreted to place an unprecedented burden on pharmacists, that of duplicating the evaluation already made by the prescriber. This shift in legal construction is unnecessary, given that pharmacists are already accountable for using their professional judgment to ensure compliance with established pharmacy laws. For these reasons, CMA recommends deleting "verify and" from proposed sections 1735(d), 1735.1(e)(1)(B), 1736(d), and 1736.1(e)(1)(B) of the second modified text. This would maintain the documentation standard established in current regulation while ensuring pharmacists retain the flexibility to perform verifications as deemed appropriate based on their professional judgment, as intended by the Board.	
3	1736(e)	Novo Nordisk	**Comment:** We support the Board's revisions to the definition of "essentially a copy" in the sterile compounding regulations for the same reasons as described in our comments regarding the updates to that definition at Section 1735(d) in the nonsterile compounding	Board staff have reviewed the comment and do not recommend any change to the proposed text. Staff note that proposed regulation Section 1735.14(a) provides that records shall be maintained as required by USP Chapter 795 and this article in a readily retrievable form. The records

#	Section	Commenter	Comment	Staff Response
			regulations. Requiring the pharmacist to verify and document the prescriber determination is consistent with FDA's 503A Copies Guidance and helps implement an important check on compounding of unapproved drug products. Additionally, consistent with our comments regarding Section 1735(d) above, we recommend adding to this Section 1736(e) the requirement that the documentation of the prescriber determination be maintained in a readily retrievable format, rather than including that requirement at Section 1736.1(e)(1). Our recommended changes to Section 1736.1(e)(1) are described directly below. **Recommended language revision:** "'Essentially a copy' of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product, except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as verified and documented by the pharmacist, between that compounded preparation and the comparable commercially available drug product. Such documentation must be maintained in a readily retrievable format."	suggested by the commenter would be covered by the provisions in Section 1736.20(a).
4	1736(g)	Marie Cottman	This definition is different than the definition of quality in Section 1735 for CNSPs, which seems odd. What is the "degree" to which PICs, DPs, and compounding personnel should aim for to meet this definition of quality? Requirements for sterility, bacterial endotoxin limits, lack of particulates, and characteristics of the preparation must already be met through the application of USP 797. Who defines the standard, the "degree," and what the	Board staff have reviewed the language and thank the commenter for raising this issue. Board staff believe the proposed text is intended to allow for the use of professional judgment by the pharmacist. However, given the comment, Board staff believe it is appropriate update the proposed regulation text to reflect the current requirements in the Board's existing regulation text CCR section 1735.1(g). 1736(g) "Quality" means ~~**the degree to which the components and preparation meets the intended**~~

#	Section	Commenter	Comment	Staff Response
			"intended specifications" are for a particular CSP? Further, even without the confusing language, the definition still has the phrase, "including but not limited to" which allows very broad enforcement. **Recommend to remove vague/undefined language and match CSP definition of Quality with CNSP definition of Quality.** (g) "Quality" means ~~the degree to which the components and preparation meets the intended specifications, complies with relevant law and regulation, and means~~ the absence of harmful levels of contaminants, including but not limited to filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, or the absence of inactive ingredients other than those listed on the master formulation record as specified in USP 797.	~~**specifications, complies with relevant law and regulation, and means**~~ the absence of harmful levels of contaminants, including but not limited to filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, or the absence of inactive ingredients other than those listed on the master formulation record as specified in USP Chapter 797.
5	1736.1	CA Rheumatology Alliance and CA Society of Plastic Surgery	We have reviewed the staff responses to our comments and continue to be concerned with the applicability of the proposed regulations on physicians and their ability to "compound" medications in their offices. Although physicians may not be under the enforcement jurisdiction of the Board of Pharmacy, we believe the proposed regulations would change the standard of care for when physicians compound medications and will not allow rheumatologists/physicians to buffer injection/ infusion medications in-office. We are interpreting the proposed regulations to require a pharmacist be present or performing the buffering of the injection/ infusion medications. Rheumatology practices/physicians would not be able to afford to employ a pharmacist for this one purpose. This would lead to rheumatology practices no longer offering this	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 to a physician. Business and Professions Code section 4170(c) makes clear that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Profession Code) with respect to its licensees. It may be appropriate for the commenter to confer with their licensing board to discuss their concerns. Board staff note

#	Section	Commenter	Comment	Staff Response
			service for our patients. Patients would then be forced to obtain their injection/infusions at a hospital or infusion center which would not only be less convenient for our patients, but it would be more expensive for the patient and the overall healthcare system. We believe it is important to note we are not aware of any issues with rheumatologists/ physicians "compounding" injection/ infusion medications. We would like to propose the Board of Pharmacy adopt the language suggested by the California Medical Association as shown below: **§ 1736.1:** In addition to the standards set forth in USP Chapter 797 and Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) the following requirements apply throughout this article. **This article shall not apply to compounding by or under the direct supervision of a licensed physician and surgeon.**	that the Medical Board of California has previously provided a written response to individuals inquiring about the applicability of the Board of Pharmacy's regulations to individuals and practices that operate under the jurisdiction of the Medical Board of California. Below is the information provided from the Medical Board - - Dear Ms. Sodergren: I understand that some concerns have been raised by stakeholders about the applicability of the Board of Pharmacy's pending compounding regulations to licensees of the Medical Board of California (MBC). Existing statute (see Business and Professions Code (BPC) section 2220.5) makes it clear that only the MBC can discipline its physician licensees. Whenever a physician is engaging in compounding (or any other action that their medical license authorizes them to perform) they must always do so consistent with the standard of care. For the purposes of MBC's enforcement program, the standard of care is established by expert testimony in the context of the facts and circumstances of a specific case. It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding, especially since some of the proposed regulations reflect what is already required for physician compounding under federal law, including, but not limited to, Section 503A of the Federal Food, Drug, and Cosmetic Act (BPC section 2225(b) allows MBC to investigate violations of federal law related to the practice of medicine). Feel free to share this message with others as you see fit who might also be concerned about the applicability of their pending regulations to the physician community. Please contact me if you have any further questions. Sincerely, Reji Varghese Reji Varghese is the Executive Director for the Medical Board of California. The Medical Board is charged with evaluating

#	Section	Commenter	Comment	Staff Response
				compounding practices and the standard of care relevant to its licensees.
6	1736.1(b)	CSHP	Public meeting discussions related to this proposed requirement have included the Board's opinion that this proposed rule is like the current requirement in CCR 1751.8(c) and deletion of this rule is a step back from a stricter rule in existence. This confounding opinion is made repeatedly while major alterations are being made after multiple and ongoing attempts by the public to request a change to an antiquated rule that is based off an old standard. USP removed the expectation for emergency use associated with emergencies and adjusted the new BUD to four hours. There is an allowance for USP to utilize immediate-use compounding in a vast variety of clinical settings. USP does not mandate that all sterile compounding take place in classified facility. USP does not require the need for emergent situations in order to perform immediate-use compounding. USP does not need to make allowances for when facilities and equipment are down because immediate-use is already available. Discussions during the Board of Pharmacy meetings have indicated that emergency-use is needed and that it would benefit patients. However, these regulations place many barriers on those who are caring for patients, that it is detrimental to those we are serving. There are no requirements for immediate-use compounding that limits its utilization for routine use. In fact, USP was changed so that it removes barriers for healthcare personnel so that they can care better for patients. The basis for the proposed requirement erroneously	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that the Board is not banning provisions for immediate use compounding. Board staff considered this issue most recently during its November 5-6, 2024, Board meeting and made significant changes to the language in previously noticed modified text to increase flexibility for licensees, including adding specific provisions for rural hospitals. Board staff note that the proposed regulation text could reduce costs that may be currently experienced stemming from the current limited provisions for immediate use compounding that exist in the Board's current regulatory provisions. The additional flexibilities being proposed in the second modified text could therefore reduce costs where such provisions for immediate use do not currently exist. A review of the public record of the 2023 minutes from the various meetings during which the regulations were developed demonstrate that public comment raised this issue of costs during a single meeting specifically related to the costs of preparation mats. Since that time the Board has responded to comments throughout the rulemaking process and modified regulation text to address some of the specific cost concerns raised where patient safety would not be impacted. Staff also note that requirements of federal law, state law, and the Chapter may all have associated costs. As an example, the Chapter describes tests that must be used, SOPs that must be developed, reviewed, etc. These are examples of costs to comply with the Chapter's requirements. Compounding facilities have a variety of practice settings and perform a variety of different types of compounding. Organizations may choose to standardize some operations across licenses operating under common ownership or control while others may not.

#	Section	Commenter	Comment	Staff Response
			presumes the utilization of immediate-use is only for emergencies. To continue with the proposed requirement, in essence, means California pharmacists will be the only licensed professionals banned from utilizing the USP immediate-use allowance while every healthcare professional in United States of America is allowed to routinely use it. The hypothetical assumption that pharmacies with cleanrooms must have an emergency plan for when sterile compounding operations are down, sounds great on paper and in theory, practically, there are just not that many options available to health systems particularly if it's a rural hospital. Elimination of immediate use authority creates additional hurdles to acquiring the medication that might be insurmountable and therefore jeopardize patient safety. The Board failed to capture the economic impact to health systems in their ISOR. The board's response to the question of "Business Impact" in ISOR states; "the board anticipates minimal ongoing costs ranging from approximately $5,700 to $15,000 per year related to administrative and maintenance workload." This statement applies to the multiple proposed regulations requiring the addition of new administrative procedures, reporting requirements, and enhanced testing. The amount stated is a gross underestimation of the true cost to health systems. Understandably the Board lacks the internal expertise to accurately reflect those anticipated costs associated with development of policies and procedures, monitoring implementation of those procedures, correctly reporting to the Board as proposed by this regulation and others, cost of monitoring visits by the Board,	Board staff agree that the Chapter does not establish limitations for immediate-use compounding; however, staff note that immediate-use provisions under the Board's regulation are available to a facility for use in several situations including in the event of an equipment failure when efforts to remediate do not remedy the issue. Board staff remain concerned that, as has been witnessed in several board investigations, some compounding facilities will default to routine immediate use provisions, placing patients at higher risk of harm. Board staff note that the types of sterile products compounded are broad, including various routes and rates of infusion, creating risks to patients if the compounding is not performed under appropriate conditions. As an example, a sterile compound for intrathecal administration can be administered over a significant period of time, e.g.,. 30 days. During this time the preparation viable growth can occur. The Board's proposed regulation text seek to strike a balance with provisions for expanded use of immediate use provisions under certain conditions while ensuring immediate use provisions do not become the standard of practice for compounding by Board licensees.

#	Section	Commenter	Comment	Staff Response
			elanced testing requirements, purchase of additional inventory for PPE, implementation of technology to support the deployment of the policies and procedures and hiring of additional staff to support compliance with the proposed regulation. **Recommendation:** Remove the requirement limiting the use of immediate-use CSP's to situations where failure to administer could result in loss of life or intense suffering due to this being deleted from the new USP 797 standards and the profound negative impact on patients. This will subsequently remove the need for reporting to the board as well as the allowance given to rural hospitals.	
7	1736.1(b)	Kaiser Perm.	Commenter requests that 1736.1(b) be stricken from the language. During the January 8, 2025 full Board meeting, the Board indicated that this regulation is necessary to prevent pharmacies from routinely preparing compounded sterile products under immediate use conditions. However, throughout the rulemaking process, the Board has not presented any evidence that immediate use compounding, when it meets the required conditions in the "Immediate Use CSPs" section of the USP chapter, presents an unacceptable risk to California patients. In fact, the USP Expert Committee designed the chapter's immediate use provisions to balance the risks (i.e. the risk of microbial contamination) associated with immediate use compounding against the risks of delaying medication administration.1 If the Board believes this regulation is necessary to prevent entities from "defaulting to immediate use provisions for all preparations," then the Board should provide	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 proposed regulation text provides significant flexibilities beyond what is currently allowed in existing regulations. Board staff disagree with the assertion that the Board's regulations in this area will shift compounding to non-pharmacy personnel. Also noted is that the commenter appears to be speculating about business operation decisions that could be made that would make compliance less safe. The Board is not able to respond to speculation on business operation decisions outside of its purview. As stated elsewhere by the Board in this rulemaking, the Board's jurisdiction is limited to the licensees within its practice act. For commenters interested in understanding the requirements for nonpharmacy personnel compounding and the requirements for those individuals and entities, it would be appropriate to contact the respective regulatory agencies.

#	Section	Commenter	Comment	Staff Response
			evidence that shows how and why the USP expert committee has erred in allowing immediate use compounding without these stipulations. Additionally, the Board did not respond to our observation in our December 6, 2024 letter that continuing to enforce these requirements will incentivize organizations to shift compounding to non-pharmacy personnel in situations in which immediate use compounding is necessary. The Board should explain how shifting compounding to non-pharmacy personnel who are not subject to the Board's oversight will improve patient safety.	Board staff notes that a variety of nonpharmacy personnel have authority to compounding including for example physicians and veterinarians. Such individuals must comply with the requirements of their regulatory agencies including for example immediate use provisions, as applicable.
8	1736.1(b)(2) & (3)	Marie Cottman	I have no objection to these sections being present, however, I do not understand the rationale of differing timelines. Both allowances provide "an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient." But a critical access hospital has 5 days to get fixed and everyone else only 2 days. If the outcome of the patient is the same, loss of life or intense suffering, why the differential time line? **Recommend to pick either 48 or 120 hours and make one rule for everyone.**	Board staff have reviewed the comment and do not recommend changes. Board staff believe that the different authorities referenced by the comment are specifically intended to address challenges facing critical access hospitals that have not have the same access to resources to ensure continuity of patient care. Staff further note that the differences in timeframe were previously established specifically in response to comments received during the 30-day comment period.
9	1736.1(d)	Wedgewood	Based on staff comments an amount of compounded drug may be furnished to a veterinarian based on the estimated need of the veterinarian as submitted on a purchase order will be considered the determination of a reasonable quantity. We appreciate the Board's recognition of Office Use (Stock) as an important service provided by pharmacies to veterinary medicine professionals and we	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. Board staff believe the proposed modified text is clear when read in its totality. (Staff note that one must read the relevant federal and state law, the USP Chapters, and the Board's proposed regulations to gain full understanding of requirements.)

#	Section	Commenter	Comment	Staff Response
			appreciate the expansion of the ability to dispense from Office Stock to 14 days. We are concerned about the continuing ambiguity of the phrase "reasonable quantity" as it remains undefined in this draft. We are not opposed to placing limitations, but a lack of definition creates ambiguity, risks inconsistent enforcement, and further calls on pharmacists to exceed their scope of licensed practice. In the Board's response to our comment it was noted, "As the commenter notes, reasonable quantity is further clarified in paragraphs (1) and (2)". We interpret this to mean that the veterinarian's purchase order indicating that the order is for office administration, or application, and for dispensing no more than 14 days' supply constitutes a reasonable quantity and will proceed under that assumption unless further clarity is provided. As such, we will not be required to make a determination of whether the licensed prescriber "fairly estimated" the days' supply ordered.	This issue was considered most recently by the Board during its January 8, 2025, discussion where the Board changes for the proposed second modified text to allow for a 7-day supply as specified. Staff further note that it appears the commenter has referenced a separate section of the law, related to CNSPs, in their suggestion that a 14-day supply is allowed. Staff believe it is important to note that a 14-day supply is not allowed under Section 1736.1 unless the CSP is a topical ophthalmic preparation, which under the proposed regulations will allow for up to a 28-day supply of such a CSP. Staff believe the commenter may be referencing the 14-day supply allowed in provisions in section 1735.1(d)(2)
10	1736.1(e)(1)	Novo Nordisk	**Comment:** We recommend that the Board amend Section 1736.1(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 17736(e), for the same reasons as described above in our comments on Section 1735.1(e)(1) of the nonsterile compounding regulations. The shortage provisions in the Second Modified Text are inconsistent with federal law and policy, and are overly permissive such that they would pose risks to patient safety and the public health. Here again, the requirement at Section 1736.1(e)(1) of the Second Modified Text that the compounding pharmacist verify and	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that the Board's provisions specifically related to the comment provide additional flexibilities for health care facilities licensed pursuant to Health and Safety Code 1250 (which includes hospitals) is consistent with the FDA guidance document 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 direct the commenter to the Modified Initial Statement of Reasons that includes the referenced FDA Guidance Document, Compounded Drug Products that Are

#	Section	Commenter	Comment	Staff Response
			document the prescriber determination of a clinically significant difference for an identified individual patient is duplicative of the requirement already stated in the definition of "essentially a copy" at Section 1736(e), and thus is unnecessary. Additionally, as noted above, we have proposed to add the requirement that documentation of the prescriber determination be maintained in a readily retrievable format to Section 1736(e), and it is therefore unnecessary here. Thus, we recommend updating Section 1736.1(e)(1) to state only the prohibition on compounding copies, and remove all other content. **Recommended language revision:** "(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, as defined at Section 17736(e) of this article."	Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act.
11	1736.1(e)(1)(B)	CMA	CMA is concerned that the Board's proposed modified text establishes a new requirement for pharmacists to "verify" that a prescribed compounded drug product produces a clinically significant difference for the medical need of an identified individual patient under specific conditions. CMA acknowledges the role of pharmacists exercising professional judgment, as outlined in Business and Professions Code (BPC) section 4306.5. However, the proposed requirement to "verify" introduces unnecessary and unintended rigidity into the process. Contrary to the Board's assertion, mandating verification in every instance of compounding a drug that is otherwise commercially available and not on a shortage list sets a prescriptive standard for how pharmacists must exercise their professional	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. 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 requires a pharmacist to verify that a prescribed medication is clinically appropriate for a patient, irrespective of whether it is a compounding medication. 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.

#	Section	Commenter	Comment	Staff Response
			judgment. The language of the regulations expressly requires pharmacists to verify the existence of a clinically significant difference for each compounded preparation in this situation, rather than allowing pharmacists to exercise their professional judgment as to when such verification may be warranted. This mandate impedes the flexibility the Board claims to seek to preserve and, as such, the language violates the clarity standard because it conflicts with the Board's description of the effect of the regulations in its response above. Pharmacists are already obligated to exercise judgment when dispensing dangerous drugs and are empowered by BPC section 733(b)(1) to refuse to dispense a prescription based on professional judgment, potential harm, or legal concerns. Eliminating the "verify" requirement from the proposed regulation would not abrogate pharmacists' statutory responsibilities but would instead maintain the flexibility pharmacists need to practice most effectively. The verification requirement would also impose significant administrative burdens on both pharmacists and prescribing physicians. For each compounded medication, pharmacists would need to collect and document proof of verified clinical significance for the prescribed drug, while physicians may be required to provide additional supporting evidence. This process could lead to delays in dispensing compounded medications, creating barriers for patients who rely on these treatments. For some patients, such delays could limit timely access to necessary therapies, ultimately harming their care. Finally, federal law, specifically 21 USC § 353a and 21 CFR Part 216, does not establish a documentation requirement, let alone a	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

#	Section	Commenter	Comment	Staff Response
			verification requirement for compounding. FDA guidance only recommends that "[…] the compounder should ensure that the determination is documented on the prescription." The guidance also clarifies that the FDA "[…] generally does not intend to question prescriber determinations that are documented in a prescription or notation." Current state regulations require pharmacists to retain the documentation of the determination of clinical significance. The Board's proposal, however, goes beyond all of these standards by mandating that pharmacists both verify and document the prescriber's determination. This additional verification obligation introduces a new requirement, not a clarification of existing state or federal statute. By creating this new regulatory standard, the proposal could be interpreted to place an unprecedented burden on pharmacists, that of duplicating the evaluation already made by the prescriber. This shift in legal construction is unnecessary, given that pharmacists are already accountable for using their professional judgment to ensure compliance with established pharmacy laws. For these reasons, CMA recommends deleting "verify and" from proposed sections 1735(d), 1735.1(e)(1)(B), 1736(d), and 1736.1(e)(1)(B) of the second modified text. This would maintain the documentation standard established in current regulation while ensuring pharmacists retain the flexibility to perform verifications as deemed appropriate based on their professional judgment, as intended by the Board.	
12	1736.1(e)(2)	Wedgewood	The reference to a specific edition of a Guidance	Board staff have reviewed the comment and do not recommend any change to the proposed text. Board staff

#	Section	Commenter	Comment	Staff Response
			Document is troubling. Recommendation: This compound shall be in compliance with current industry guidance. the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022. We are grateful for the Board's clarification on the inclusion of the AMDUCA reference. While we appreciate the clarity provided, we are concerned that a direct reference to a Guidance Document (GFI 256), including a specific dated version, could be problematic should that document be modified or repealed. Rather than reference a specific document, we would recommend removing the language or changing it to simply reflect "applicable industry guidance" as noted below.	note that to meet the requirements of the APA, the proposed regulation text must be specific about the standards of practice that will be enforced. If those standards are contained in a particular document, it must be referenced. The text cannot include a standard that might be contained in a future document.
13	1736.1(e)(4) Listed as 1736(e)(4) in submitted comment	Marie Cottman	This is duplicated in proposed 1736.10(e) (the section on sterility– more appropriate location). It also could be more direct if it needs to be in 2 places. **Recommend to remove 1736(e)(4) in favor of leaving in 1736.10(3).** **If not removed, consider rewording:** (e) In addition to prohibitions and requirements for compounding established in federal law, no CSP may be compounded that: (4) Requires end product sterilization ~~unless sterilization occurs~~ <u>that cannot be completed</u> within the same licensed compounding location.	Board staff have reviewed the comment and believe the commenter is referring to section 1736.1(e)(4). Board staff do not recommend a change to the proposed text. Board staff note that the language in the referenced regulation text is discussing the same concept, however being discussed in different context.
14	1736.1(g) Listed as 1736(g) in submitted comment	Marie Cottman	This is largely not "in addition to." 1707.2(c)When oral consultation is provided, it shall include at least the following: (1) directions for use and storage and the importance of compliance with directions;... (4) precautions for preparation and administration by the patient…	Board staff have reviewed the comment and believe the commenter is referring to section 1736.1(g)(1). Board staff note, that consistent with the provisions if 1707.2, a pharmacist is required to initiate a consultation; however, a patient may decline the consultation to the pharmacist.

#	Section	Commenter	Comment	Staff Response
			Further, 1707.2(e) allows an out for when the patient or the patient's agent refuse consultation. By having this special consultation for CSPs in section 1736, it becomes a SHALL ***always***, even when the patient doesn't want it. This rule would be much better added to 1707.2 as an additional requirement. As a licensee, it is always frustrating to have to identify multiple sections that address the same requirements! **Recommend to remove and add rulemaking to add this language to 1707.2**	
15	1736.4(e)	Marie Cottman	This is not congruent with 1736.1(b)2&3. **Recommend to reword:** (e) No CSP shall be compounded if the compounding environment fails to meet criteria specified in law or the facility's SOPs unless designated as immediate use only in compliance with 1736.1(b)(2) or 1736.1(b)(3).	Board staff have reviewed the comment and thank the commenter for their recommendation to clarify the language. Board staff offer the following: 1736.4 (**~~f~~ e**) No CSP shall be compounded if the compounding environment fails to meet criteria specified in law or the facility's SOPs, **unless such compounding is being performed consistent with immediate use provisions.**
16	1736.6	Marie Cottman	Comment: Great that this reference is incorporated– glad to know the standard! However, access to this standard costs $295. As many compounders are conducting their own monthly sampling, we will have to purchase yet another reference. It is NOT readily available.	Board staff have read the comment and do not recommend a change to the proposed text. Staff note that the commenter does not appear to be recommending changes to the proposed text. As noted in the Board's Initial Statement of Reasons, "CETA guidelines establish an industry-based minimum set of criteria appropriate for performance evaluation and certification of facility and environmental controls used for compounding sterile preparations. This minimum set of criteria are necessary to ensure consistent and repeatable testing at all facilities."
17	1736.8	Marie Cottman	This is not "in addition to the requirements of USP Chapter 797," rather it is a restatement of proposed rule 1736.17. Having the same rule in two locations just complicates things! **Recommend remove, 1736.17 is clear enough.**	Board staff have reviewed the comment and do not recommend a change to the proposed text. As was stated in the staff response to a similar comment received during the 30-day comment period, inclusion in this section provides clarification to the regulated public that SOPs must address this practice and serves as a reminder.

#	Section	Commenter	Comment	Staff Response
18	1736.9(d)	Novo Nordisk	**Comment:** We appreciate the Proposed Rule's provisions requiring Certificates of Analyses (COAs) for API used to compound sterile products. We offer three recommendations to further bolster the Proposed Rule's provisions on COAs. 1. We recommend that the Board reinsert reference to excipient components to ensure that all components used to compound sterile products are accompanied by a COA. Excipient components in compounded products can cause dangerous adverse events and result in serious harm to patients. For example, FDA published a Compounding Risk Alert after receiving an adverse event report concerning a patient who experienced cardiac arrest and died after IV administration of a curcumin emulsion product compounded by ImprimisRx.11 FDA identified the presence of an impurity in PEG 40 castor oil, an excipient used in the compounded product that may have caused the adverse event. The PEG 40 castor oil used was ungraded and not suitable for human consumption or therapeutic use. FDA thus warned against the "risks associated with compounded drugs, particularly those that use non-pharmaceutical grade components and ingredients lacking a USP monograph." The Board can help to protect against these risks by reinserting COA requirements for excipient components used to compound sterile products. 2. We recommend that the Board adjust the Proposed Rule's carveout for components of commercially available drug products to ensure that the carveout only applies to ingredients sourced from and provided by the manufacturer of the commercially	Board staff have reviewed the comments and do not recommend any changes to the proposed text. Staff note that in response to prior comments received, the Board agreed to remove explicit language related to excipient components. As the Board noted in its response to comments, a pharmacist must remain knowledgeable of current practice standards and legal requirements while exercising professional judgment. Failure to do so could constitute unprofessional conduct. Staff notes that the proposed regulation text establishes the requirements for a COA consistent with the commenter recommendation. While Board staff agree with the examples provided by the commenter, the Board's compound regulations span a variety of different settings. The Board is generally seeking to align with federal law and supporting guidance documents. It appears that the commenter is suggesting that the Board's regulations expand beyond the provisions of federal law in section 503A.

#	Section	Commenter	Comment	Staff Response
			available drug product. Requiring the COA with the specified content in all other circumstances is critical to ensuring that ingredients used by compounding facilities do not lead to unsafe and ineffective compounded drugs. 3. We recommend that the Board add a requirement that the COA of any API that claims to be a component of an approved drug show that the API was manufactured by the process specified in the labeling of the approved drug. The importance of this requirement is particularly acute for the bulk "semaglutide" used in compounding. The FDA-approved labeling for semaglutide medicines explains that the "peptide backbone is produced by yeast fermentation." Unlike the yeast-produced semaglutide in NNI's FDA-approved semaglutide medicines, the "semaglutide" in compounded drugs is produced using synthetic semaglutide unaffiliated with any approved application. Use of such API can introduce peptide-related impurities and other complexities and expose patients to safety and effectiveness risks. Indeed, testing revealed that compounded "semaglutide" samples contained high levels of impurities. This data reinforces the importance of requiring that the COA demonstrate that any API that claims to be a component of an FDA-approved drug was manufactured by the same process described in the FDA-approved drug labeling. The Board should thus (1) ensure that all components used to compound sterile products, including excipients, are accompanied by a COA; (2) limit its exemption to circumstances where a compounding	

#	Section	Commenter	Comment	Staff Response
			facility sources and obtains its API from the manufacturer of a commercially available drug product; and (3) require that the COA show that any API that claims to be a component of an approved drug was manufactured by the process specified in the labeling of the approved drug. Adhering to these standards is critical to ensure that patients do not receive unsafe and ineffective compounded products that are unaffiliated with approved drug products. **Recommended language revision:** 1. "(d) All APIs used to compound a CSP shall be manufactured by an FDA-registered facility. All APIs and excipient components used to compound a CSP shall be accompanied by a Certificate of Analysis (COA) and be suitable for use in sterile pharmaceuticals. A COA that includes the compendial name, where one exists, the grade of the material, and the applicable compendial designations on the COA, must be received and evaluated prior to use, unless components of the CSP are commercially available drug products that are sourced from and provided by the manufacturer of the commercially available drug product. The COA for any API used to compound a CSP that claims to be a component of an FDA-approved drug must show that the API was manufactured by the process specified in the labeling of the FDA-approved drug. When the COA is received from a supplier, it must provide the name and address of the manufacturer. An API and excipient components provided with a COA without this data shall not be used in a CSP."	

#	Section	Commenter	Comment	Staff Response
19	1736.9(d)	PCCA	Recommend: Remove the language: "When the COA is received from a supplier, it must provide the name and address of the manufacturer. An API provided with a COA without this data shall not be used in a CSP." Rationale: See comment in response to Section 1735.7(c)(1). **1. No Legal or Regulatory Requirement for Manufacturer Information on COAs:** Neither the FDCA nor any FDA implementing regulation—or even a non-binding guidance document—includes a "requirement for the COA" from a supplier to disclose the manufacturer name or address. Under the FDCA the sole requirement for COAs is that compounded drugs must be accompanied by valid COAs for their bulk drug substances to qualify for exceptions to the FDCA. Specifically: - 21 U.S.C. § 353a(b)(1)(a)(iii) requires that compounded drugs must be accompanied by valid COAs to qualify under Section 503A exemptions. - 21 U.S.C. § 353b(a)(2)(D) similarly requires valid COAs for bulk drug substances under Section 503B exemptions. Neither the FDCA nor FDA regulations impose any obligation to include the manufacturer's information on a COA. Instead, the FDA has long accepted the practice of suppliers providing COAs that incorporate quality testing data from the suppliers themselves as well as data from the manufacturer's own quality testing. **2. FDA Guidance Does Not Impose Such a Requirement:**	Board staff have reviewed the comment and do not recommend changes to the proposed text. The Board previously considered these comments on several occasions, including as part of its discussion during the November 5-6, 2024, Board Meeting. As was noted at that time, Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments. Staff note that while existing law provides flexibility to record the manufacturer under limited circumstances, continuation of the current provision is not appropriate as it hampers the ability of a facility to respond appropriately in the event of a product recall. Staff further note that the Board's proposed regulation text is more explicit than the Chapter for the reasons cited elsewhere in this response. Staff note that the Chapter requires either the recording of the manufacturers or vendors; however, in separate guidance issued by the FDA, the facility needs to have transparency into the supply chain and awareness of the manufacturer (where the manufacturer and vendor are different.) The FDA has released guidance in this area, including the importance of compounders knowing their suppliers - - https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipientssuppliers. Lastly, requiring the identity of the manufacturer of a component to a compounder who is compounding with that component without requiring more information be provided does not appear to be requiring the disclosure of a trade secret under Civil Code section 3426.1(d). Moreover, vendors can take steps when contracting with compounders to protect the information related to their business arrangements with manufacturers. Staff refer the commenter to the underlying data portion of the Modified Initial Statement of Reasons, which includes the above referenced FDA guidance document.

#	Section	Commenter	Comment	Staff Response
			FDA guidance documents related to compounding further underscore the lack of any requirement to include manufacturer information on COAs. **The FDA Guidance for Industry: Pharmacy Compounding of Human Drug Products Under Section 503A** (June 2016) states only that compounded drug products must be accompanied by valid COAs for each bulk drug substance. There is no mention of manufacturer information being required on the COA. While the nonbinding **FDA Guidance for Industry: Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients** *recommends* including the manufacturer's name and address on COAs in the context of cGMP compliance for outsourcing facilities, it has no implication here as it applies solely to outsourcing facilities operating under Section 503B of the FDCA. It does not apply to compounding pharmacies operating under Section 503A, which are expressly exempt from cGMP requirements. See 21 U.S.C. § 353a(a) (exempting 503A compounded formulations from cGMP requirements imposed under 21 U.S.C. § 351(a)(2)(B)). This distinction is critical. cGMP compliance is irrelevant to Section 503A compounding pharmacies, and the FDA has recognized that requiring manufacturer information on COAs is not necessary to meet the requirements of Section 503. **3. Unintended Negative Impacts:** Mandating the inclusion of manufacturer information on COAs, as proposed by the California Board of Pharmacy, would impose unnecessary burdens on compounding pharmacies and suppliers alike. The harmful consequences of the proposed regulations	

#	Section	Commenter	Comment	Staff Response
			include (1) exposing proprietary sourcing strategies—which are considered trade secrets—in violation of California law, and (2) a regulation that diverges from federal standards and guidance, creating unnecessary confusion and inconsistency for suppliers and compounding pharmacies operating across multiple jurisdictions.	
20	1736.9(d)	Marie Cottman	This is a misplaced rule! It belongs in the rules that wholesalers must comply with. The inspectors are aware that PCCA will not provide original COA nor reveal the manufacturer, except when requested by a Board Inspector. PCCA has a rigorous process to vet manufacturers, including that they are registered with the FDA. Further, they have a process of validating their wholesaler's COAs and rejecting components that don't meet standards (even if the COA says it does). **Recommend to move this requirement to BPC Article 11 in the Wholesaler chapter for rules.**	Board staff have reviewed the comment and do not recommend a change to the proposed text. Board staff note that the requirements contained in the proposed regulation text is consistent with the FDA guidance in this area. As was included in the Board's prior response to the proposed regulation text in this area, the FDA has released guidance including the importance of a compounder knowing their supplier. Staff note that suppliers are under the jurisdiction of the Board.
21	1736.9(e)	Novo Nordisk	**Comment:** We recommend that the Board revise its provisions in 1736.9 related to the conditions under which sterile compounding can occur. By adopting this recommendation, the Board will align its Proposed Rule with Federal Food, Drug, and Cosmetic Act section 503A(b)(1)(A). We also recommend that the Board add a definition for "component of a drug approved by the FDA" to ensure that API used to compound sterile drugs is the same API used to manufacturer FDA-approved drug products. In addition, for the reasons noted for section 1736.9(d) above, the Board should add a requirement that API that claims to be a component of an approved drug must be manufactured by the process specified in the labeling of the approved drug.	Board staff have reviewed the comments and do not recommend any changes to the proposed text. Staff note that the Board does not need to add a definition of component as recommended because a pharmacist must remain knowledgeable of current practice standards and legal requirements while exercising professional judgment. Failure to do so could constitute unprofessional conduct. The Board is seeking to align with federal law and supporting guidance documents. It appears that the commenter is suggesting that the Board's regulations should further restrict the provisions of federal law in section 503A.

#	Section	Commenter	Comment	Staff Response
			Recommended language revision: 1736.9: "(e)(1) Except as provided in (2) or (4), when API is used to compound a CSP, it shall – (i) comply with a USP monograph; (ii) if such a monograph does not exist, be an API that is a component of a drug approved by the FDA; or (iii) if such a monograph does not exist and the API is not a component of a drug approved by the FDA, be listed in 21 C.F.R. § 216.23." *[NEW]* "(4) A drug product may be compounded if authorized by a public health official in an emergency use situation for a patient-specific compounded sterile preparation. (5) API used to compound a CSP that claims to be a component of an FDA-approved drug must be manufactured by the process specified in the labeling of the FDA-approved drug." 1736: *[NEW]* "(i) 'Component of a drug approved by the FDA' means an API that is the same as the API used in the manufacture of the approved drug, ."	
22	1736.11(c)	CSHP	Current language in CCR 1735.3 below has a provision for CSPs compounded in health facilities to prevent delays in care to acutely ill patient, i.e. infections, cancer, critical care, etc. The current language states: (F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply.	Board staff have reviewed the comment and do not recommend changes to the proposed text. Staff note that this issue has been considered by the Board on numerous occasions most recently during the January 8, 2025, Board meeting. As was previously noted, current regulations provide an exemption to the compounding record requirement. Staff do not believe that the exemption is still appropriate. Staff note that inspections reveal that health systems and other facilities generally maintain this information within its electronic system or other documentation. Recalls can occur requiring action at the patient level. Maintaining this information is essential to identify impacted patients. Collection of this information also allows facilities to maintain documentation of compliance

#	Section	Commenter	Comment	Staff Response
			(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile preparations compounded in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference. Caring for patients in the fast-paced dynamic environment of a hospital is hampered by this restrictive proposed rule. Every additional requirement for documentation and additional information takes pharmacy staff away from patient care while not adding value for patient safety. To help pharmacy staff and hospitals take care of patients, we propose a change to our original proposal below. **Recommendation (BOLD):** We once more reiterate the comments by both us and others at various stages through this rulemaking process that USP standards adequately provide for safe and quality compounding of medications. The addition of this regulation exceeds the national standards in a manner that fails to demonstrate the benefit to patients. Add back the language above: 1736.11 Master Formulation and Compounding Records, subsection(c): **(6) Exempt from the requirements in this paragraph are sterile preparations compounded for administration within twenty-**	with manufacturer approved labeling provisions. The changes made in the modified text rprovided further clarification that the information required in this subsection does not need to be maintained in a single document. Such an approach provides flexibility in how a pharmacy maintains this information. Staff note that the Chapter, Section 11.2 requires a compounding record for each CSP. There is no exemption for hospitals in the Chapter. The request from the commenter to provide an exemption would not meet the minimum requirements of the Chapter.

#	Section	Commenter	Comment	Staff Response
			four (24) hours to a single patient in a health care facility licensed under section 1250 of the Health and Safety Code.	
23	1736.11(c)(2)	PCCA	Recommend: Remove the clause entirely. Rationale: See comment in response to Section 1735.7(c)(1).	Board staff have reviewed the comment and do not recommend changes to the proposed text. The Board previously considered these comments on several occasions, including as part of its discussion during the November 5-6, 2024, Board Meeting. As was noted at that time, Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments. Staff note that while existing law provides flexibility to record the manufacturer under limited circumstances, continuation of the current provision is not appropriate as it hampers the ability of a facility to respond appropriately in the event of a product recall. Staff further noted that the Board's proposed regulation text is more explicit than the Chapter for the reasons cited elsewhere in this response. Staff note that the Chapter requires either the recording of the manufacturers or vendors; however, in separate guidance issued by the FDA, the facility needs to have transparency into the supply chain and awareness of the manufacturer (where the manufacturer and vendor are different.) The FDA has released guidance in this area, including the importance of a compounders knowing your suppliers - - https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipientssuppliers. Lastly, requiring the identity of the manufacturer of a component to a compounder who is compounding with that component without requiring more information be provided does not appear to be requiring the disclosure of a trade secret under Civil Code section 3426.1(d). Moreover, vendors can take steps when contracting with compounders to protect the information related to their business arrangements with manufacturers

#	Section	Commenter	Comment	Staff Response
				Staff refer the commenter to the underlying data portion of the Modified Initial Statement of Reasons which includes the above referenced FDA guidance document.
24	1736.17(a)(2)	Novo Nordisk	**Comment:** Aligned with our comments for section 1735.11(a)(2) above, NNI recommends that the Board require that SOPs describe written procedures for the surveillance, receipt, evaluation, and reporting of adverse drug experiences involving sterile compounded products. **Recommended language revision:** *[NEW]* "(G) Written procedures for the surveillance, receipt, evaluation, and reporting of adverse drug experiences to the Board."	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comment received. The Board's compounding regulations establish the minimum standards for compounding. While staff agree that written procedures for surveillance, receipt, evaluation and reporting of adverse drug experiences to the Board may be appropriate for some facilities, it does not appear necessary for all compounding practices.
25	1736.17(a)(2)(E)	Marie Cottman	1736.9(f) does not exist in the most recent version of the proposed rules. **Recommend to remove.**	Board staff have reviewed the comment and thank the commenter for highlighting this error that occurred when renumbering section 1736.9. To address this issue, Board staff recommend the following change: 1736.17(a)(2)(E) The methods by which the pharmacist compounding or supervising the compounding pursuant to section 1736.9**(e)(2)(f)** related to use of a bulk drug substance published in the section 503A Category 1 bulk substances list, will ensure each lot of the bulk drug substance is representatively sampled per USP Chapter 1097 (bulk powder sampling procedures), tested, and found to be in compliance with at least:
26	1736.17(a)(2)(E) & (F)	Medisca	Medisca agrees with the Board's proposed amendment to Section 1736.17(a)(2) to include subsection (F), allowing compounders to use documentation as evidence of testing required by subsection (E). Medisca respectfully requests that the Board further amend Section 1736.17(a)(2)(E) to account for the fact that the testing requirements therein are applicable at different	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. The second modified text included changes requested by the commenter. Staff believe the proposed regulation text is clear about the requirements to establish SOPs in this area and that compounding facilities have flexibility in determining how to implement the provisions through the development of the SOPs. Board staff would be concerned about including additional regulation text that could reduce the flexibility

#	Section	Commenter	Comment	Staff Response
			stages of the compounding process. Namely, testing required under subsections (ii) and (iii) can be performed on the bulk drug substance by manufacturers and/or wholesalers, while testing required under subsections (i) and (iv) is more appropriately performed on the compounded product by the compounder. Whether or not testing required by subsections (i) and (iv) is performed by the manufacturer and/or wholesaler, the tests will need to be ran and confirmed again on the compounded product. Medisca respectfully requests that the Board amend the regulations to provide that documentation, like the Certificate of Analysis, will be considered sufficient to satisfy subsections (ii) and (iii) whenever the required testing was conducted. However, if any of the required tests were not conducted by the manufacturer and/or wholesaler, the onus should be on the compounder to ensure that both the bulk drug substance(s) used and the compounded product meet all of the requirements.	intended for compounding facilities to determine the best means by which to operationalize the requirements.
27	1736.18(c)	CSHP	The board did not demonstrate that it understood and considered the comment in that it only responded to the part where 3 business days was recommended. There was no acknowledgement of understanding of our concern that the language seems to suggest that the review must be completed within a 72 hours timeframe. We pointed out that a review can start within 72 hours but it can take longer to complete once further investigation is needed. We would like to recommend again that the word "shall start" be added to the language.	Board staff have reviewed the comment and believe the intent of the regulation text is clear, in that the proposed regulation text does not specify that the investigation into the complaint must be completed within 72 hours; rather the regulation text states that the complaint shall be reviewed within 72 hours of receipt. To best address the issue raised by the commenter, however, Board staff offer the following change be made: 1736.18 (c) In addition to subsection (b), **the pharmacist-in-charge shall initiate a review of any ~~all~~** complaints made to the facility related to a potential quality problem with a CSP and **any ~~all~~** adverse drug experiences ~~events~~ **~~shall~~**

#	Section	Commenter	Comment	Staff Response
			The way that the proposed regulation is written, seems to suggest that the review must be completed within 72 hours since it states that "such review shall be documented and dated as defined in the SOPs." The proposed language requirement for a documentation and dating of the review together with the preceding sentence's requirement for review within 72 hours from the receipt of the compliant could be seen as requiring the review to be completed within the 72 hours timeframe. A requirement of 72 hours may not provide sufficient time for pharmacies to thoroughly investigate and determine root causes. It is reasonable to expect that a review after a complaint be started within three business days. Investigation could take longer than this due to many factors involved in such an investigation that needs to be looked at. Many of these may not be available or apparent within this timeframe. **Recommendation (BOLD):** We recommend that the intent of this proposed regulation be clarified with the following proposed language: (c) In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse drug experiences shall be reviewed by the pharmacist-in-charge **and shall start** within 72 hours of receipt of the complaint or occurrence of the adverse drug experience. Such review shall be documented and dated as defined in the SOPs.	~~**be reviewed by the pharmacist-in-charge**~~ within 72 hours of receipt of the complaint or occurrence of the adverse drug experience. Such review shall be documented and dated as defined in the SOPs. Staff note that nonsubstantive conforming changes in other areas of the third modified text is appropriate.