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1	1736(d)	CMA	CMA remains concerned that the Board's new proposed requirement for pharmacists to "verify" that a compounded drug produces a clinically significant difference for a patient creates an undue burden and restricts the professional judgment the Board intended to preserve. Mandating verification for every instance of compounding a commercially available drug that is not on a shortage list establishes a rigid, prescriptive standard. This contradicts the Board's stated goal of maintaining flexibility, and, as such, the language violates the clarity standard because it conflicts with the Board's description of the effect of the regulations in its formal response to members of the public regarding this issue. Pharmacists are already required to use their professional judgment in dispensing compounded drugs. Eliminating the "verify" requirement from the proposed regulation would not abrogate pharmacists' statutory responsibilities, but would instead maintain the flexibility pharmacists need to practice most effectively. As written, the requirement could be interpreted to mean pharmacists must contact prescribers for verification in all cases where they compound a commercially available drug, leading to unnecessary delays in patient care. As a result, the lack of clarity within this requirement risks limiting access to necessary treatments, particularly in cases where compounded medications are essential alternatives to commercially available drugs. Federal law does not impose a verification or documentation requirement on pharmacists. Instead, the FDA, in non-binding guidance, recognizes documentation of a prescriber's determination as sufficient. The Board's proposal, by contrast, creates a new obligation	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the comment does not address modifications made in the third modified text. Board staff also note that the Board has previously considered the comment and determined that a change was not appropriate. Board staff refer the commenter to the Board's prior response to this comment from this commenter, in row 2 available here, and includes, "Board staff have reviewed the comment and do not recommend a change to the proposed text because modifications in the second modified text addressed it. Staff note that this issue was previously considered by the Board, most recently during the January 8, 2025, Board Meeting. As approved by the Board during that meeting, the second modified text 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. 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."

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			without clear justification, increasing administrative complexity without improving patient safety.	
2	1736(e)	Eli Lilly	Some of the Board's proposed revisions to the defined term "essentially a copy" are necessary and appropriate to ensure that patients are treated with a compounded drug only when those patients cannot be served by an FDA-approved medicine. The "essentially a copy" ("EAC") prohibition is one of the key legal prohibitions that prevents compounding pharmacies from selling knockoffs of FDA-approved medicines. For it to serve its intended purpose (which is to prevent end runs around the new drug approval requirement in the guise of compounding), the EAC prohibition must be broad and must not be easily evaded. To that end, Lilly offers the following comments. 1. We applaud the Board's proposal to define "essentially a copy" to include any compounded drug "that includes the same active pharmaceutical ingredient(s) (API(s))" as an approved medicine. This broad definition will ensure that the EAC prohibition protects the public health as it was intended by ensuring that compounding pharmacies cannot evade the prohibition through minor or pretextual formulation changes. 2. We also applaud the Board's proposal to limit the exception to the EAC prohibition to situations where the pharmacist has "verified and documented" that the compounded drug will produce a "clinically significant difference" for the specific patient. This verification also is	Board staff thank the commenter for the information that is in support of the Board's proposed modified text. Board staff have reviewed the comments and do not recommend any change to the proposed text of the regulation.

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			essential to protect the public health and prevent evasion. All too often, providers and pharmacists (often working together pursuant to contracted commercial arrangements) have attempted to evade the EAC prohibition through sham prescriptions and other illicit measures. Requiring the pharmacist to use his or her professional judgment to verify that the compounded drug makes a real change that will be clinically significant will help to ensure that patients receive FDA-approved medicines whenever possible. We support the Board's proposed revision as it provides the necessary and appropriate flexibility for pharmacists to use their professional judgment in determining whether a compounded drug is essentially a copy. Contrary to the suggestion by other commenters, exercising that professional judgment does not impinge a prescriber's judgment, but rather preserves the ability for pharmacists to exercise their clinical judgment as well. As the Board has previously observed, federal law requires that the compounded drug produce a significant difference for the patient. The proposed revision makes it clear that the pharmacist must independently verify, and then document, that the compounded drug will indeed produce a clinically significant difference from an FDA-approved medicine for a given patient.	
3	1736(e)	CSHP	We add our voice to others who commented on this section who pointed out their concern with the wording of this section. We appreciate the board's position that the intent is to rely on the professional judgement of the pharmacist.	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the comment does not address modifications made in the third modified text.

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			the regulation and wish to point out that this section has the potential to be misinterpreted as written, both currently and in the future. It is important to get this right so that the intent is clear and does not cause confusion. The wording of "Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product," could be interpreted to mean that ANY compound being made is defined as essentially a copy of a commercially available drug product. The trouble here is that any compounded drug that has the same API as a commercially available drug product will violate this regulation. Using the example of a hospital pharmacy that compounds 10 bags of Oxytocin 30 Units in 500ml Normal Saline for use in their Labor and Delivery (L&D) unit. The Oxytocin bag is made by using three 1ml vials of Oxytocin 10units/1ml. By the definition above, it will be a violation of this proposed regulation since these bags are made in bulk and they include the same API as the commercially available drug product of Oxytocin 1ml. These bags are made in bulk, so, by definition, it is not being compounded specifically for an identified individual patient that produces for that patient a clinically significant difference. These bags are being used for almost every patient that will have a delivery on the unit, so one cannot argue that it is being made for a specific individual patient. This proposed regulation, if it is read simply for the way it is stated, will imply that the pharmacist verifying the order will need to go through a process of verifying with the prescriber and then documenting each and every order for Oxytocin bags that the change	Board staff note that the commenter appears to be describing what would be considered sterile compounded preparations. The Board notes that the FDA guidance does not address the practice described by the commenter. The Board's proposed regulation text provides greater flexibility to pharmacists in the healthcare setting where the FDA guidance is silent. The Board also refers the commenter to the provisions included in 1736.1(e)(1)(A) and (B) that provide additional flexibilities for health care facilities.

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			from the commercially available 10 unit per 1ml vial to a compounded 30 unit per 500ml Oxytocin bag produces a clinically significant difference for each individual patient. In the ISOR, the board states that the FDA guidance document is being utilized to provide guidance regarding this definition. 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	

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			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 contain an API that is commercially available (even though it is available in a completely different non-sterile dosage form). According to the definition, a hospital making a batch of oral suspension from tablets on a regular basis for its neonatal of pediatric unit, will be making essentially copies of the API in the tablets and will have to call and verify with the prescriber and then document the self-evident information that the change was made for each and every identified individual patient that produces for that patient a clinically significant difference. We are sure that we can all agree that this is not the intent of the regulation. By adding the crucial elements of strength and route it narrows the definition and it is much clearer and is aligned with both the FDA and board's intent. This addition of language provides clarification while still allowing flexibility for the pharmacist to use professional judgement. By adding the components that aligns with FDA guidance, it becomes clear that it will the same as federal statute and guidance, and we recommend that this regulation be deleted. While all involved currently in the creation and comments for the definition of "essentially a copy" may have a grasp and understanding of the intent of this proposed regulation, we must take the multiple comments from all stakeholders as an indicator that there will be future misunderstanding and misinterpretations	

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			of this language. It is of the utmost importance to recognize that ten to fifteen years from now these interpretations and intent will be forgotten, and the only guidance left to enforce are the words as written. We are sure that the current board would not want future board members and staff to enforce this rule under the misunderstandings that we and others took great pains to point out at this moment in time. **Recommendation:** (d) "Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product, **the API(s) have the same, similar, or an easily substitutable dosage strength; and the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug** except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as **verified and documented** by the **pharmacist**, between that compounded preparation and the comparable commercially available drug product.	
4	1736.1	B. Go	The response by the Board that both proposed as well as existing regulations on compounding, as currently worded, do not infringe on the practice of compounding by non-pharmacist licensees under the jurisdiction of other California professional boards, is not satisfactory for the following reasons: 1. You responded with comments from only one board, the Medical Board of California,	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the comment does not address modifications made in the third modified text. The Board has previously considered this and similar comments and provided responses throughout the rulemaking, including for example the response provided in row 5 available here, which included in part, "Board staff have

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			which only regulates MD's. This does not apply to other licensees such as DO's, nurses, ND's, dentists, and veterinarians, who may also have the right to compound medications in-office without a pharmacist and without interference by the Board of Pharmacy. Furthermore, even the MD's right to compound is still in jeopardy based on current wording of the Board's regulations, for the following reasons: a. The Medical Board's letter noted that only the Medical Board has the right to discipline its licensees. This would only apply if the licensee was being disciplined as an MD, not if they were being disciplined as a person practicing pharmacy without a license. Again as previously stated, the Board of Pharmacy's jurisdiction is to regulate the practice of pharmacy, and therefore practicing pharmacy without a license would fall within their purview. Both currently existing regulations as well as the proposed changes exclude non-pharmacists from being able to compound, specifically defining the practice of compounding as that which occurs by a pharmacist ONLY. (See proposed regulation 1736.1a (a): "For the purposes of this article, sterile compounding occurs, by or under the direct supervision and control of a licensed pharmacist, pursuant to a patient specific prescription, unless otherwise specified in this article." And see currently existing regulation: CCR 1735(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist")	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." The Board refers the commenter to Business and Professions Code section 4170 as well as the Board's jurisdiction. The Board respectfully recommends that the commenter review the Board's Initial Statement of Reason that describes the Board's jurisdiction to gain a better understanding of the applicability of the Board's regulations. The commenter also appears to be providing comments about a statutory proposal related to the regulation if IV hydration clinics, which is outside the scope of this regulation. Staff refer the commenter to the Board's proposed statutory proposal for an understanding of the Board's legislative proposal. Staff note that the language in the statutory proposal includes explicit language that it would not apply to a facility for which a professional director is on site while sterile compounding occurs.

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			b): The Medical Board's letter notes: "It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding." - they admit that your regulations may affect MD's practice of compounding. I'm not sure why you have so much resistance to adding wording which would only help to clarify the limitations of your role, and would limit the confusion and ambiguity which the current wording is creating. Instead, you have specifically chosen to include wording which is overly broad, and which implies that compounding only may be performed by a pharmacist. 2. You claim that regulations specifically state you cannot regulate other practitioners 3. Furthermore, you have not directly responded to previous comments that noted the contradiction between your stance on the above and the fact that you are currently making preparations to attempt to regulate what you refer to as 'IV hydration clinics'. These clinics do not have pharmacists, however they do have other non-pharmacist licensees who have the right to compound. The term 'IV hydration clinic' itself is not well-defined by the board, and it is foreseeable that the board could choose to include any medical office that provides IV hydration or IV nutrients in this category, offices in which compounding might be conducted by any of a variety of types of licensed non-pharmacist practitioners who should not be under the purview of the Board if it were not for the current language in your	

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			regulations. Therefore, the claim that your compounding regulations do not or will not interfere with compounding by non-pharmacist licensees in disingenuous. Please do note and respond to this paragraph in full in your reply as well.'	
5	1736.1(b)	Kaiser	In their response to our January 24, 2025 comment letter, Board staff intimated that Kaiser Permanente was speculating about the likely second-order effects of this proposed regulation.3 The Board can call these comments speculation if it wishes, but we contend that we are engaging in deductive reasoning to assess the incentives and behaviors that the proposed regulations are likely to precipitate—something we assume the entire Board should do throughout any rulemaking process. Even if the Board is not interested in critically evaluating these proposed regulations for likely second-order effects, as a responsible pharmacy stakeholder, Kaiser Permanente will continue to highlight the probable unintended consequences of these unnecessary regulations. In the case of this proposed regulation, if there are additional restrictions placed on pharmacy licensees engaging in immediate use compounding, it would naturally follow that some entities would choose to have non-pharmacy personnel take over immediate use compounding to avoid the burden of meeting the Board's regulations. As such, if the Board's desired outcome is that non-pharmacy personnel are more frequently engaged in compounding sterile products for Californians, then we believe that the Board has written a regulations that will achieve that result. If, instead, it is the Board's intent to incentivize immediate use compounding by pharmacy personnel who complete extensive	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the comment does not address modifications made in the third modified text. The Board has previously considered this comment. The Board's prior response remains appropriate and is included in row 7 available here which include, "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." Board staff notes that a variety of nonpharmacy personnel have authority to compound including for example physicians and veterinarians. Such individuals must comply with the requirements of their regulatory agencies. Further, as a reminder, current provisions of the law related to immediate use compounding are MORE restrictive than the proposed regulation text. Staff routinely perform inspections

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			training and competency validation and are subject to the Board's oversight, then we strongly encourage the Board to delete this proposed regulation and enforce the USP standards for immediate use compounding.	at facilities and report that even under the current more restrictive conditions, compounding continues to be performed by pharmacy personnel.
6	1736.1(b)	CSHP	We would like to continue our objections to this proposed regulation for the reasons that we and others have pointed out both in writing and written comments up to this point. As stated before, we object to the proposed regulation since it would severely limit pharmacies' ability to utilize the immediate-use provision to only those limited situations where the failure to administer such CSP could result in loss of life or intense suffering of an identifiable patient. This continues to narrow the scope of application of the immediate use provisions of USP to a point where it is practically unusable. We and others continue to point out the unintended consequences that this rule has been responsible for in the past, such as shifting compounding to disciplines that do not fall under the jurisdiction of the board. We are concerned that the board's response to stated concerns negates the complexity of health system operations by implying our practices are inefficient and potentially in accurate. . The Board's responses, at times, fails to provide evidence for the continued support of the proposed regulations that have been identified by the regulated entities as potentially harmful to the patients we serve. We object to the proposed regulation for the reason that the regulation lacks clarity regarding the reporting expectations. It is not clear if a pharmacy must report each and every use of equipment failure and its associated utilization of immediate use compounding. During a conference with	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the comment does not address modifications made in the third modified text. Further, the Board has previously considered this comment. The Board respectfully refers the commenter to the Board's prior response in row 6, available here which includes, "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

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			multiple pharmacy compounding leaders from all across the state, this regulation was discussed and it became quickly apparent that there were different interpretations of the reporting requirement. Some thought that they would only have to report to the board if their equipment failure lasts past 48 hours. While others thought they should report every single equipment failure and immediate use utilization. Some were also wondering about scenarios that come up regularly for many pharmacies. For example, if a cleanroom pressure is out of specification and staff stop compounding while waiting for it to either self-correct or call engineering staff to fix. While it is being fixed, there is an order for an IV that must be started within an hour. The pharmacist makes it under the proposed immediate use allowance and shortly thereafter the cleanroom pressure is within normal limits. Is the expectation that this be reported? The next day, engineering has a scheduled HVAC maintenance. While they are working on the HVAC, an immediate use IV is being made. Is this then reportable again to the board? Is the board prepared to start receiving these regular reports from hospitals all over the state? Is this the intended consequence? We recommend that the board clarify their expectations via regulations for clarity to the regulated public. The board's proposal for immediate use in instances where there may be equipment and engineering control failures is inadequate. It does not account for both catastrophic failures of the equipment and environment or for catastrophes like natural disasters. We once more reiterate our stance that the additional allowance for critical access hospitals only	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." The Board's prior response remains appropriate to respond to a portion of the comment. Further, Board staff do not agree with the recommendation to expand provisions specifically related to critical access hospitals to additional hospitals as proposed. The current proposed regulation text provides flexibilities for critical access hospitals that experience unique challenges. Board staff again note that the proposed regulation text expands current provisions for immediate use compounding. Board staff further note that the commenter's second recommendation to generally expand immediate use provisions to address an immediate patient need exceeds the provisions of USP 797. Although staff believe the language is clear, submission of the comment suggests otherwise. Board staff are recommending the following changes. 1736.1(2) If the sterile compounding equipment or environment fail(s) to meet any required specification, **after attempts to remediate pursuant to the facility's SOPs are unsuccessful,** an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may only be

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			addresses the problem partially. We object to this partial addressing of this problem and again recommend that the board recognize that there are many rural hospitals that are not designated as critical access hospitals. These hospitals can run into the exact same problems with equipment and engineering controls as critical access hospitals with equally devastating consequences. There are even standalone, single owner hospitals in metropolitan areas without the benefit of belonging to a health system that can be impacted. While we highly recommend that subsection (b) be changed to our recommendation below under the bolded heading of 'Recommendation", absent an acceptance of this recommendation, we recommend that the allowances of subsection (3) be changed to: 3) If the sterile compounding equipment or environment fail(s) to meet any required specification in a ~~critical access~~ hospital **that are not within 40 road miles of a hospital of the same corporate ownership** , ~~as defined in the Social Security Act 42 U.S.C. 1395i-4 section (c)(2)(B)~~, after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering or an identifiable patient. This provision may be used for 120 hours after such failure(s). All such failures shall be documented in accordance with facility's SOPs and shall be reported to the Board within 72 hours. 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.	used for ~~24~~ **48** hours after such failure(s). All such failures must be documented in accordance with facility's SOP, ~~and~~ ***Failures requiring use of immediate use provisions*** shall be reported to the ~~**BOP**~~ **Board** within 72 hours ***of the transition to immediate use provisions***. **(3) If the sterile compounding equipment or environment fail(s) to meet any required specification in a critical access hospital, as defined in the Social Security Act 42 U.S.C. 1395i-4 section (c)(2)(B), after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering ~~or~~ of an identifiable patient. This provision may be used for 120 hours after such failure(s). All such failures shall be documented in accordance with facility's SOPs, ~~and~~ *Failures requiring use of immediate use provisions* shall be reported to the Board within 72 hours *of the transition to immediate use provisions*.**

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			We object to the requirement for reporting immediate use to the board. As stated on multiple occasions by us and others during the rulemaking process, we once more reiterate our position that the newly proposed requirement to report each instance of immediate use compounding associated with a temporary engineering control malfunction will place a burden on both pharmacy personnel and board staff. The benefit of reporting each minor malfunction to the board is questionable and it is difficult to see how reporting to the board a temporary operational decision to utilize immediate-use compounding to care for patients while an issue is addressed with engineering controls will add value and enhance the safety of the public. Reporting of issues to regulatory agencies are usually reserved for serious matters and only those issues that are within the regulatory agency's' jurisdiction to act. It must be pointed out that immediate use compounding is an allowable action under USP797 standards, it is utilized routinely, regularly and safely in healthcare practice settings worldwide. Performing a simple and safe immediate-use compound for a patient by a pharmacy licensee while an engineering control malfunction is being addressed is not serious enough to warrant a report to the board. There is a possible unintended consequence of entities shifting this simple temporary task to disciplines functioning outside the scope of these regulations and the jurisdiction of the Board. Requiring reporting of each instance of compounding of an immediate-use CSP will lead to increased administrative requirements, increased personnel needs, and will have the unintended	

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			consequence of potentially diverting resources from patient care activities or worse patients will be unable to access compounded medications due to onerous requirements and fear of inability to comply. We recommend that this requirement be deleted. It is concerning that other than stating that "this is existing language at section 1751.8(e)…" there are no reasons provided in the ISOR for the requirement that CSPs used for immediate administration be limited to situations where the failure to administer could result in loss of life or intense suffering. This requirement was created based on the old USP standards when there was limited understanding of the applicable microbiological principles and the wide clinical barriers it creates as it relates to immediate use. It is important that the board consider the negative impact on patient care that this antiquated rule creates. Since the ISOR does not address the objective and scientific reasons for the limitation on immediate use, we recommend that the regulation be deleted. The expectation of an emergency plan to provide compounding services when the hospital's sterile compounding operations are down are ideal and hospitals are required by federal regulations to have emergency plans. However, the regulations are implying the hospital must have a backup cleanroom. This is a multi-million dollar investment which is not possible for most hospitals and especially for rural and stand alone hospitals. . The impact of the proposed regulations will have significant impact on hospitals financial solvency with unintended consequences to patient care. Elimination of low complexity immediate use provision creates additional hurdles to acquiring the	

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			medication that might be insurmountable and therefore jeopardize patient safety. We wish to provide the following realistic example: when a rural non-critical access hospital pharmacy has a sterile compounding airflow hood malfunction, and the replacement hood must be ordered and shipped, they can use immediate use compounding for two days. After this they must stop compounding. What is a pharmacy supposed to do then? Think about it, a licensee has the drugs in their hands, but they cannot go through the simple process of mixing it together in a few seconds to treat a patient. . In the absence of a workable solution, we recommend that the immediate use regulation be deleted. We object to the boards business impact numbers. The immediate use regulation alone will cause a loss in income totaling millions of dollars if a hospital must close their doors and ship patients out to a hospital with a working cleanroom. 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	

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			Board as proposed by this regulation and others, cost of monitoring visits by the Board, enhanced environmental and personnel 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. The Board further states in the ISOR under the header of "Business Impact" as it relates to the issue of cost the following: "This initial determination is based on the absence of testimony to that effect during the public discussion and development of the proposed regulation." The public meetings mandate testimony be limited to a few minutes and attendees tend to focus their input on the specific wording of the proposed regulation and not the cost. It is incumbent on the Board to actively pursue input from those that can accurately project the cost to health system of the proposed regulation. The Board should, during public meetings, or by other means seek input from experts who can inform the Board's ISOR development as it relates to both "Business Impact" and Economic Impact Assessment" to ensure the ISOR is an accurate reflection of the impact to health systems on cost and health care access. We wish to further point out that the board has not responded to our comments regarding the economic impact of this proposed rule since they have not approached senior health system leaders who are best situated to assess and assist them with economic impact of this rule. Neither has the board shared their assessment of how this rule will increase their cost of enforcement of the proposed rule.	

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			USP 797 provides sufficient guidance in their improved and updated standards for immediate-use compounding, and we once more recommend that the board to require USP's standards and not engage in additional regulations that are not based on an articulated and proven evidence that such proposed regulations will enhance patient safety efforts beyond the national standards. We appreciate the complexities of regulating sterile compounding across the diversity of health system procedures and processes and we would like to invite board members and staff to consider doing site visits to gain a greater appreciation for how health systems promote patient safety and quality of compounded drug preparations. We would be happy to set up those site visits with our members. We agree that the routine utilization of immediate use in a hospital is an inappropriate practice. CSHP and our members have the same goals for patient safety as the board. It is unfortunate that some have engaged in this practice and now the many law-abiding facilities and pharmacy licensees must suffer the consequences. To account for the unfortunate choices of the few, whilst not punishing the majority we would recommend a more measured approach by limiting the time that an immediate use sterile compound can be used for up to 12 hours maximum from the time that compounding starts. This way the concerns for patient safety is addressed while it is also not so restrictive to the vast majority of ethical and law-abiding licensees. It also has the added benefit that it will not lock both licensees and board staff in a burden of reporting and administrative duties.	

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			Additionally, this problem does not have to be solved with multiple layers of regulation that attempts to solve for endless 'what-if' scenarios. As we have taken pains to point out in the aforementioned, these regulations will be creating insurmountable obstacles to patient care, which could in practice only be overcome by licensees making immediate use sterile compounds which would be a violation of the regulations if enacted. Please see our recommendation below. **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. **Recommended Text:** (b) CSPs for direct and immediate administration shall only be compounded in such quantity as is necessary to meet the immediate need of the patient. A compound made for immediate use shall have a maximum beyond use date of 4 hours and shall expire after 12 hours.	
7	1736.1(b)(2)	Sutter Health	Clarify the highlighted requirement for reporting to the Board within 72 hours. Does the Board intend for licensees to report all failures that result in using the provision for immediate use, or all sterile compounding equipment or environment failures that do not meet any required specification, regardless of whether immediate use CSPs are compounded? Please clarify the reporting expectation with clear language.	Board staff have reviewed the comment. Staff note that the Board determined it was appropriate to establish specific provisions for critical access hospitals in response to previously submitted comments. It is important to note that the provisions for such hospitals allowed for five days (as opposed to 10 days as suggested by the commenter). Board staff note that the proposed regulation text requires failures to be reported to the Board where the transition to immediate use provisions is necessary. Although staff believe

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			compounding locations, as discussed during allowance, onsite compounding with shorter beyond-use dates for immediate use is much preferred over offsite compounding and access designation should allow for 10 days, while other facilities can also require this reasonable time to mitigate a major failure appropriately by implementing a robust, reporting to the Board. Please do not create differing standards for critical access versus nation and within all other non-pharmacy care settings, immediate use is an allowable federal documented competency. The goal of the immediate use provision is to ensure patient access with a higher standard of care. If you keep a differing standard, provide for allowance to all hospitals without an alternative	changes. (1736.1(2) If the sterile compounding equipment or environment fail(s) to meet any required specification, **after attempts to remediate pursuant to the facility's SOPs are unsuccessful,** an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may only be reported to the ~~**BOP**~~ **Board** within 72 hours ***of the transition to immediate use provisions***. **(3) If the sterile compounding equipment or environment fail(s) to meet any required specification in a critical access hospital, as defined in the Social Security Act 42 U.S.C. 1395i-4 section (c)(2)(B), after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering ~~or~~ of an identifiable patient. This provision may be used for 120 hours after such failure(s). All such failures shall be documented in accordance with** ***provisions* shall be reported to the Board within 72 hours *of the transition to immediate use provisions*.**
8	1736.1(e)	CSHP	The FDA does not classify repackaging or admixing a commercially available product according to its package insert as compounding activities. Consequently, section 1736.1 (e)'s prohibition on compounding a copy or essentially a copy does not apply to these activities. There should be the ability for facilities that repackage Category 3 CSP's. The products are repackaged under sterile conditions while adhering to stringent sterility standards and they also perform container	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Board staff note that the recommendation offered by the commenter would run contrary to USP 797 provisions which provides, "Sterile compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile preparation." Board staff believe it may be helpful for the commenter to also consider the provisions of the FDA guidance document,

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			closure potency studies that exceed basic requirements. These facilities minimize contamination risks through advanced testing protocols and high-quality control, offering enhanced safety and efficacy for sterile preparations. For example repackaging from sterile manufactured vials into syringes that contain doses that are ready to be administered safely without further manipulation. Add the following language: (D) the drug is a sterile product, repackaged or admixed in a centralized hospital repackaging facility in a USP Category 3 compliant facility, and those sterile products are only used within that health system at that health system's acute care facilities.	"Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities" available here.
9	1736.1(e)(1)	Novo Nordisk	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. In doing so, we ask that the Board reconsider the positions stated in the Staff Responses to NNI's comments to the Second Modified Text. The shortage provisions in the Third 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 Staff Response to NNI's prior comments does not defend the reference to the ASHP list, which is inconsistent with FDA's 503A Copies Guidance. For the same reasons as explained above, to best protect patient safety and the public health,	The Board has previously considered this comment and refers the commenter to the Board's prior response included in row 10, available here, which includes in part, "**Board staff have**

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			compounding of unapproved drug products, we also ask the Board to remove, or at the very least significantly narrow, the broad permission for health care facilities to compound copies. Again, these provisions are inconsistent with FDA's 503A Copies Guidance and are not supported by FDA's 503A Hospital and Health System Compounding Draft Guidance, as described above. 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 1736(e) of this article. Documentation by the pharmacist that the compounded drug product produces a clinically significant difference for the medical need of an identified individual patient, as provided for at Section 1736(e) of this Article, must be maintained in a readily retrievable format."	
10	1736.1(e)(1)	Partnership For Safe Medicines	The board's proposal to expand the list of medicines that can be compounded beyond medicines on the FDA shortage list (section 1736.1(e)(1)) raises serious concerns about patient safety and the integrity of the pharmaceutical supply chain:. **Concerns About the Expansion of Rules on Compounded Medications** 1. **The FDA Should Be the Sole Authority on Drug Shortages** o The **FDA drug shortage list** is compiled based on rigorous criteria and is overseen by experts responsible for ensuring medication safety and efficacy. o Unlike the FDA, ASHP is a respected trade organization but is not a regulatory body. Including its shortage list in determining which	Board staff have reviewed the comment and do not recommend a change to the proposed text based on this comment. The Board has previously considered similar comments. The Board's prior response remains appropriate in response to comments 1 and 3, that included in part, "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 include hospitals), is consistent with the FDA's 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

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			drugs may be compounded undermines the authority of the FDA and risks inconsistent or overly broad application of compounding exceptions. 2. **Compounded Medications Carry Greater Risks** o Compounded drugs are not FDA-approved, meaning they do not undergo the same stringent review process for safety, efficacy, and quality. o Expanding the eligibility for compounding beyond the FDA shortage list increases the likelihood that patients will receive medications with varying potency, sterility, and consistency issues. 3. **The "Cannot Obtain from Manufacturer or Wholesaler" Standard Is Vague and Problematic** o The proposed rule change introduces a broad standard that could be exploited to justify compounding for economic or convenience reasons rather than genuine medical necessity. o Without clear, enforceable definitions, healthcare facilities and compounding pharmacies may interpret the rule differently, leading to unnecessary compounding when FDA-approved alternatives are still available. 4. **Undermining the Drug Supply Chain Security Act (DSCSA)** o The **DSCSA was enacted to ensure the traceability of medications** and reduce counterfeit drug risks. However, compounded drugs are exempt from its serialization requirements. o Expanding compounding eligibility increases the presence of untraceable medications, posing additional risks of counterfeiting, contamination, and supply chain vulnerabilities.	law while ensuring hospitals have additional flexibility to take care of patients." Board staff respectfully refer the commenter to the Modified Initial Statement of Reasons that includes the referenced FDA Guidance Document, Compounded Drug Products that Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act. Specifically related to comment 2, the Board agrees that compounded medications carry greater risks. The Board's compounding regulations are intended to address the risks to patients by generally clarifying and making more specific federal requirements including guidance documents and provisions in national standards. Related to comment 4, the Board agrees that compounded products are exempt from the DCSCA provisions. This is federal law and exceeds the scope of the Board's authority to regulate provisions of the DCSCA as the Board's requirements for e-pedigree were preempted by federal law. Finally, related to a determination of medical need (comment 5), the Board agrees that a determination of medical need by a medical provider is necessary. As the Board does not regulate prescribers, the requirement was removed from the proposed regulation text. The authorized healing arts board responsible for oversight of the prescriber would be responsible for evaluating for compliance with the medical need determination established in federal law. The Board appreciates the concerns raised by the commenter and recognizes that the FDA has a significant role in the regulation of GLP-1s. This responsibility was underscored in a recent joint letter from the National Association of Attorneys General, dated February 19, 2025. The Board continues to monitor information released from the FDA related to these products including conditions of

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			o Today using the **NABP's Pulse** product, you can instantly scan a branded or generic pharmaceutical product and confirm it is real or not. In fact this tool was just used in Arkansas to detect a unit of counterfeit Ozempic. **This is not possible to do with a compounded product**, as these are not serialized. As compounding has grown from a pharmacist compounding a product and handing it to a patient to what it is today, **the danger of the lack of traceability has grown** as well. **5. The determination of medical need for a compounded medication should involve the prescribing practitioner** o The proposal to remove the tripartite requirement that the prescribing practitioner, the compounding pharmacist, and the dispensing pharmacist all agree that compounding this product is based on medical need is a step back. It does not seem wise to cut the prescribing physician out of the decision-making of patient care here, and we oppose this. Shortages in the GLP-1 space have created significant patient safety issues that the FDA has repeatedly warned both patients and healthcare professionals about, including but not limited to: ● Lax labeling standards leading to dangerous dosing problems; ● Substantiated concerns about compounders using unapproved ingredients; and ● Warnings to compounders about sterility issues. Conclusion Adverse event reporting is a vital patient safety tool that saves lives. The proposed rule changes	insanitary conditions. The Board assesses for insanitary conditions for all compounding practices, not just those related to GLP-1s.

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			jeopardize the well-being of Californians and weakens the integrity of the pharmaceutical supply chain. Furthermore, the inclusion of ASHP's drug shortage list weakens patient protections by introducing a non-regulatory decision-making process into compounding rules. **We strongly urge the California State Board of Pharmacy to reject this dangerous proposal and uphold its commitment to protecting public health.**	
11	1736.1(e)(1)	Pacific Research Institute	The Board is considering regulations that would eliminate the necessity for pharmacists to review and report adverse drug experiences to the Board for compounded drugs. Further, the rule seeks to broaden the circumstances under which drugs can be compounded during a shortage. Specifically, the Board's proposed regulations would permit compounding of copies when a drug product appears on the American Society of Health System Pharmacists (ASHP) list, and when a health care facility "cannot obtain" a drug from the manufacturer or wholesaler. These modifications are ill-advised as they will raise serious patient safety concerns. Unlike sponsors of FDA-approved medications, which are subject to extensive postmarketing reporting of adverse drug experiences, compounding pharmacies do not engage in surveillance or evaluation and are already subject to less stringent adverse event reporting requirements. As the Food and Drug Administration notes, "compounded drugs should only be used in patients whose medical needs cannot be met by an FDA-approved drug. Unnecessary use of compounded drugs may expose patients to potentially serious health risks. For example,	Board staff have reviewed the comment and do not recommend a change to the proposed text based on this comment. The Board has previously considered similar comments. The Board's prior response remains appropriate in response to comments 1 and 3, that included in part, "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 include hospitals), is consistent with the FDA's 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 respectfully refer the commenter to the Modified Initial Statement of Reasons that includes the referenced FDA Guidance Document, Compounded Drug Products that Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act. Board staff note that current law, Business and Professions Code section 4127.1 established mandatory reporting requirements to the board including adverse effects reported

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			poor compounding practices can result in serious drug quality problems, such as contamination of a drug that contains too much or too little active ingredient. This can lead to serious patient injury and death." The safety concerns that have arisen with respect to compounded GLP-1 drugs (the brand name drugs of Ozempic, Wegovy, Mounjaro and Zepbound) validate the FDA's concerns and exemplify the potential adverse consequences that will likely arise from these proposed changes. In response to the unprecedented demand for GLP-1 medications, compounding facilities are mass-marketing unsafe and unapproved compounded semaglutide products to patients, thereby increasing the risks of unreported adverse events. Due to the proliferation of compounded GLP-1s in Illinois, for example, the state's attorney general issued a consumer alert warning patients "to be aware that many sellers advertising these name brand medications are instead offering unapproved versions of these products that may put people's health at risk." In South Carolina the state's attorney general issued a consumer alert warning that "unapproved and compounded products can be risky for consumers because they are not reviewed by FDA for safety, quality, or effectiveness." It further notes that "many unscrupulous sellers are making misleading health claims and promoting unapproved and compounded tirzepatide and semaglutide products in formulations that have never been evaluated by any regulatory agency and may never have been tested in humans at all."	or potentially attributable to a pharmacy's sterile drug product. This section also requires reporting to the MedWatch program. The Board shares the patient safety concerns raised by the commenter and believes the current statutory requirements remain appropriate.

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			In support of the AGs' concerns, the FDA's Adverse Event Reporting System (FAERS) database reports 695 cases of adverse events associated with compounded semaglutide. Of those cases, 506 were classified as serious adverse events, 159 reported hospitalization, and 13 involved deaths. These rates are more than triple the number of adverse events for all compounded drugs in 2022. Unfortunately, the actual harm could be much worse. According to the FDA "it is likely that adverse events from compounded versions of these drugs are underreported" because compounding pharmacies are not required to report adverse events to FDA. Many more patients may have already experienced serious harm associated with compounded semaglutide. As a result of these adverse events, the FDA has issued risk alerts concerning compounded semaglutide and tirzepatide. The FDA further noted that some of these reports and hospitalizations may relate to dosing errors of compounded GLP-1s, including several patients who mistakenly administered five to 20 times more than the intended dose of compounded semaglutide. The experience with GLP-1s argues for increasing, not decreasing, the reporting requirements for adverse events associated with compounding medicines. It also argues for stricter controls over their use. Conclusion The broad exceptions that the Board of Pharmacy are considering are inconsistent with federal law and could lead to compounding of	

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			unapproved drug products when the FDA-approved drugs are available to meet the patients' needs. Consequently, it is important that the Board retain and re-incorporate a reference to adverse drug experiences within the Standard Operating Procedures (SOPs) for compounders. This will ensure that pharmacists are responsible for reviewing complaints related to potential quality issues and adverse events. It is equally essential that Board mandate compounding facilities to report adverse events associated with sterile and nonsterile compounded products by reinstating the clause pertaining to adverse drug experiences	
12	1736.1(e)(1)(B)	CMA	CMA remains concerned that the Board's new proposed requirement for pharmacists to "verify" that a compounded drug produces a clinically significant difference for a patient creates an undue burden and restricts the professional judgment the Board intended to preserve. Mandating verification for every instance of compounding a commercially available drug that is not on a shortage list establishes a rigid, prescriptive standard. This contradicts the Board's stated goal of maintaining flexibility, and, as such, the language violates the clarity standard because it conflicts with the Board's description of the effect of the regulations in its formal response to members of the public regarding this issue. Pharmacists are already required to use their professional judgment in dispensing compounded drugs. Eliminating the "verify" requirement from the proposed regulation would not abrogate pharmacists' statutory responsibilities, but would instead maintain the flexibility pharmacists need to practice most effectively. As written, the requirement could	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the comment does not address modifications made in the third modified text. Board staff also note that the Board has previously considered the comment and determined that a change was not appropriate. Board staff refer the commenter to the Board's prior response to this comment included in row 11, available here, which includes, "Board staff have reviewed the comment and do not recommend a change to the proposed text because modifications in the second modified text addressed it. 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 compounded 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

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			be interpreted to mean pharmacists must contact prescribers for verification in all cases where they compound a commercially available drug, leading to unnecessary delays in patient care. As a result, the lack of clarity within this requirement risks limiting access to necessary treatments, particularly in cases where compounded medications are essential alternatives to commercially available drugs. Federal law does not impose a verification or documentation requirement on pharmacists. Instead, the FDA, in non-binding guidance, recognizes documentation of a prescriber's determination as sufficient. The Board's proposal, by contrast, creates a new obligation without clear justification, increasing administrative complexity without improving patient safety.	judgment in all aspects of practice and not simple defer their judgment to another individual. This is obligation is memorialized throughout Pharmacy Law, including notably BPC Section 4306.5. Should it be helpful, Board staff refer the commenter to some specific provisions of the law that establish specific requirements for pharmacists to evaluate prescriptions prior to dispensing including as examples: Health and Safety Code section 11153 Business and Professions Code 733 Title 16, California Code of Regulations Section 1707.3"
13	1736.1(e)(1)(D)	D. Burger	(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP may be compounded that: (1) Is essentially a copy of one or more commercially available drug products, unless: (A) that drug product appears in an American Society of Health-System Pharmacists (ASHP) Drug Shortages List or FDA Drug Shortages Database of drugs that are in short supply at the time of compounding and at the time of dispensing, or in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained, or (B) The pharmacist determines verifies and documents that the preparation produces a clinically significant difference based on the medical need of an identified individual patient, as determined by:	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Board staff note that the recommendation offered by the commenter would run contrary to USP 797 provisions: "Sterile compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile preparation." Board staff believe it may be helpful for the commenter to also consider the provisions of the FDA guidance document, "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities" available here.

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			(ii) the compounding pharmacist, and (iii) the dispensing pharmacist(s). (C) Documentation describing the conditions in subsections (1)(A) & (1)(B) is maintained in a readily retrievable format (D) the drug is a sterile product, repackaged or admixed in a centralized hospital repackaging facility in a USP Category 3 compliant facility, and those sterile products are only used within that health system at that health system's acute care facilities. Rationale: The FDA does not classify repackaging or admixing a commercially available product according to its package insert as compounding activities. Consequently, section 1736.1 (e)'s prohibition on compounding a copy or essentially a copy does not apply to these activities. There should be the ability for facilities that repackage Category 3 CSP's. The products are repackaged under sterile conditions while adhering to stringent sterility standards and they also perform container closure potency studies that exceed basic requirements. These facilities minimize contamination risks through advanced testing protocols and high-quality control, offering enhanced safety and efficacy for sterile preparations. For example, repackaging from sterile manufactured vials into syringes that contain doses that are ready to be administered safely without further manipulation. Additional Rationale: In additional support, Category 3 facilities that have extended BUDs in place must test their products to establish that extended BUD. The	

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			testing includes testing for; 1. Stability, 2. Sterility, 3. Container closure integrity, 4. pH, 5. Appearance , 6. Particulate, 7. Endotoxin. In addition, the Category 3 facilities are held to the highest standard in USP 797 as far as personnel training, environmental testing, and end batch sterility testing. With this testing rigor in place the maximum allowable BUD is 60 days at room temperature which. The mandated quality control present in a Category 3 facility is recognized and as a result would be a safe environment to produce any available sterile product on the market and therefore should be carved out as an exception to section 1736.1 prohibitions. In addition, if the NEW regulations include the activity of repackaging into the definition of sterile compounding, then a clear incongruency would exist as there is no such exclusion detailed in the repackaging of oral solids, liquids or in the outlined scope of practice found in a CHP repackaging license.	
14	1736.1(e)(2)	M. Cottman	Recommendation: Amend to remove the last sentence: ~~This compound shall be in compliance with the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022.~~ Comments: "Shall be in compliance with a [document]" This statement is far too non-specific as the GFI document contains Intro, Background, Paperwork Reduction Act and Appendices that link to websites. Specifically, what part of the 21 page GUIDANCE document SHALL we comply with? And what happens to 1735.1(e)(2) when the document changes or goes obsolete (yes the OMB has an	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the comment does not address modifications made in the third modified text. Staff note that reference to the GFI included in 1736.1(e)(2) was made in response to commenters requesting that the language reference the document. Prior to recommending inclusion of the GFI, Board staff conferred with an expert on veterinary practice who confirm incorporation of the document was appropriate.

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			expiration date on the document)? If you want additional required items that compounders should comply with for veterinary preparations, please don't make us hunt and peck for the language you are looking for, spell it out. Labeling? Documentation? Bulk Drugs for office use? Reporting ADEs to the FDA? What specifically are you looking for???? It describes "The circumstances under which, at this time, FDA does not generally intend to take enforcement action against drugs compounded from bulk drugs substances for violations of the FD&C Act's requirements for approval, adequate directions for use, and CGMPs." The FDA states that it "generally does not intend to take enforcement action against" NINE (9) times in the document! GFI 256 is written as GUIDANCE, not as regulation nor law. It describes "The circumstances under which, at this time, FDA does not generally intend to take enforcement action against drugs compounded from bulk drugs substances for violations of the FD&C Act's requirements for approval, adequate directions for use, and CGMPs." Several items that are vague or open to interpretation. As well as statements that outright conflict with each other. Do compounders comply with the statement on pg 5 that: "drugs compounded from bulk drug substances violate the FD&C Act because they are not approved or indexed, are not made according to CGMP, and cannot satisfy the FD&C Act's adequate directions for use provision (which requires, among other things, that a prescription drug have FDA-approved labeling). "	

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			Or the statement also on pg 5: "[the] FDA recognizes that there are circumstances in which no FDA-approved or indexed drug (including the extralabel use of an FDA-approved animal or human drug) can be used to treat an animal with a particular condition. In those limited circumstances, an animal drug compounded from bulk drug substances may be a medically appropriate treatment. " Do we, as licensees assume that we should replace BOP wherever we see FDA in the document such as "This guidance describes: • The types of drugs compounded from bulk drug substances that FDA[BOP] has determined present the greatest risk to human and animal health and intends to make priorities for enforcement action; and • The circumstances under which, at this time, FDA [BOP[does not generally intend to take enforcement action against drugs compounded from bulk drugs substances…"	
15	1736.1(f)	M. Cottman	**Recommendation:** Remove this section. ~~(f) Prior to allowing any CNSP to be compounded within a pharmacy, the~~ pharmacist-in-charge shall complete a self-~~assessment consistent with the requirements~~ established in section 1715. **Comments:** Redundant. This is not making a new rule, it is just reminding compounders to follow existing regulation 1715 to complete a self-assessment. To comply with 1715, a PIC must fill out the form before July 1 of every odd numbered year… What is it that you want done differently? We are already so highly regulated! Wasting text on re-stating existing laws doesn't help clarify anything.	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the comment does not address modifications made in the third modified text. Board staff note that section 1715 established a requirement to complete the self-assessment specifically related to compounding.

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			Further, a more appropriate approach would be to create a separate rule making process to address adding the Compounding Self Assessment requirement to section 1715, in line with all the other references to Self Assessments since CCR 1735.2[k] will be repealed if this text is adopted.	
16	1736.1(g)	M. Cottman	**Recommendation:** Amend redundant language. (g) In addition to the provisions in section 1707.2 of this Division, consultation includes ~~proper use,~~ ~~storage,~~ handling, and disposal of the CNSP and related supplies furnished. **Comments:** 1707.2 already includes "(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;" Restating these items here does not clarify anything.	Board staff have reviewed the comment and do not recommend changes based on the comment received. As was discussed previously by the Board, the provisions in 16 CCR 1707.2 do not include requirements related to handling and disposal nor do they require consultation on provisions for related supplies furnished.
17	1736.2(d)	Sutter Health	Argument Against Mandatory Removal for Aseptic Competency Failures Establish Different Standards: Differentiate between initial and ongoing aseptic manipulation assessments and those with non-technique related aseptic testing failures. A blanket requirement for all compounding scenarios does not align with USP standards and due to the rigor of testing can significantly impact critical operations without determining that the failure was related to poor aseptic practices (new fingerprint and surface samples have many opportunities more for potential contamination over technique related failure). Observation Over growth:	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the comment does not address modifications made in the third modified text. Staff note that the board has carefully considered the provisions and do not believe it is appropriate to allow a person that has failed any aspect of aseptic manipulation to continue compounding. Appropriate aseptic manipulation is fundamental to safe compounding practices. Board staff also believe it is important to reiterate that USP 797 Chapter underscores the importance of aseptic manipulation competency evaluation specifically providing that prior to beginning compounding, personnel must successfully complete an aseptic manipulation competency evaluation

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			The standard should emphasize the importance of observing aseptic technique adherence and correcting deviations. Growth results should not automatically disqualify a compounder, as contamination may not always be technique-related. Consider allowing SOP Alternative Mitigations: Implement SOP-driven mitigations for non-technique related contamination, such as unexpected growth on TSA plates when techniques adhered to compounding protocols. Allow flexibility in SOPs to address different contamination scenarios. Proposed Actions Require Immediate Retraining and Supervision: Retrain affected personnel immediately on aseptic techniques. Allow them to continue working under direct supervision until competency is re-established. Enhanced Monitoring: Increase environmental monitoring and conduct additional or follow up aseptic competency personnel sampling. Implement additional checks, like more frequent glove and gown changes, to minimize contamination risks. Removing experienced compounders from duties for non-technique related failures is impractical and disrupts operations. Adopt a balanced approach with targeted retraining and enhanced monitoring to maintain safety and efficiency.	and further the Chapter establishes the frequency for ongoing competency evaluation. These requirements establish the timeframe within which the evaluation must be completed. Staff note that an individual who fails any aseptic manipulation can compromise the integrity of the product. Staff further note that the proposed regulation text includes provisions that allow for an individual who has failed aspects of aseptic manipulation to continue oversight of compounding for 30-days. This time period was established to allow for retraining and sufficient time to process the results of the retesting.
18	1736.8	M. Cottman	Recommendation: Remove this section. Comment: I reiterate my previous comments that this is addressed adequately in proposed 1736.17.	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the comment does not address modifications made in the third modified text.

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			The rationale provided by Staff after the last revision that "this section serves as a reminder," is a substandard rulemaking justification. I respectfully submit that reminders should not be drafted into rules or regulations. Instead, create an FAQ! We already have to comply with hundreds of pages of rules, regulations, and guidelines. Don't create unnecessary extra text by putting the same rule in two places, it just creates confusion.	, The Board has previously considered this comment and determined that a change was not appropriate. Board staff refer the commenter to the Board's prior response to this comment, that is in row 17 available here that includes "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."
19	1736.9(d)	Novo Nordisk	We appreciate the Proposed Rule's provisions requiring Certificates of Analyses (COAs) for API used to compound sterile products. We ask the Board to reconsider or clarify its positions offered in the Staff Responses to NNI's comments to the Second Modified Text. First, we recommend that the Board reconsider removing language relating to excipient components to ensure that all components used to compound sterile products are accompanied by a COA. While we agree with the Board that pharmacists must be knowledgeable of current practice standards and legal requirements, excipient components in compounded products can cause dangerous adverse events and result in serious harm to patients regardless of any one pharmacist responsible for compounding a drug. 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.6 FDA identified the presence of an impurity in PEG 40 castor oil, an excipient used in the compounded product that may	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the comment does not address modifications made in the third modified text. Staff note this comment has been previously considered by the Board. Board staff refers the commenter to the Board's prior response included in row 18 available here that includes "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."

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			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."7 The Board can help to protect against these risks by reinserting COA requirements for excipient components used to compound sterile products. Second, in the Staff Responses, the staff notes that "the proposed regulation text establishes the requirements for a COA consistent with the commenter recommendation." We request that the Board confirm that the staff response intends to convey that the Proposed Rule's carveout for components of commercially available drug products only applies to ingredients sourced from and provided by the manufacturer of the commercially available drug product. We also ask that the Board consider adopting the recommend language revision below to make the Board's position even clearer. Third, we recommend that the Board reconsider adding 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	

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			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.8 The peptide-related impurities9 identified in the samples have the potential to stimulate immunological processes to produce antibodies against semaglutide peptides, potentially posing immunogenicity risks that can lead to serious and life-threatening reactions like anaphylaxis.10 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) confirm that its exemption is limited to circumstances where a compounding 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: "(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	

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			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."	
20	1736.9(d)	M. Cottman	Recommend to move this requirement to BPC Article 11 in the Wholesaler chapter for rules. Comment: Board Staff is incorrect when they say that this proposed rule "is consistent with the FDA Guidance in this area." This statement is FALSE! Here is the statement from the FDA https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipients-suppliers "FDA Urges Compounders to: ● know your bulk drug substance and excipient suppliers ● know the quality of the materials you get from your suppliers, including what testing the supplier does to determine the quality of the components you purchase	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the comment does not address modifications made in the third modified text. Staff note that this comment has previously been considered by the Board. Board staff respectfully refer the commenter to the Board's prior response in row 20 available here, that includes, "**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.**"

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			● meet the conditions regarding bulk drug substances in sections 503A and 503B of the Federal Food, Drug and Cosmetic Act, including: ○ API compliance with applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph standards ○ sourcing API from FDA-registered facilities ○ valid certificates of analysis ○ excipient compliance with applicable USP or NF monograph standards" NOTE There is no requirement NOR recommendation of the FDA to have the compounder actually see the COA from the original manufacturer. In contrast Compounders are urged to know their SUPPLIERS and have a VALID COA!!! As is evidenced by the number of chemicals that are rejected by valid wholesalers (i.e. PCCA and Medisca), the original COA is not always sufficient. I reiterate that this is still a misplaced rule! IF you are concerned about your licensed wholesalers, repackagers, and suppliers of providing poor quality chemicals for your compounders, go to the source and require that wholesalers must comply with.	
21	1736.9(e)	Novo Nordisk	Proposed Rule with federal standards. For that reason, we ask that the Board align with federal law by revising its provisions in 1736.9 related to compounding can occur. By adopting this Proposed Rule with Federal Food, Drug, and Cosmetic Act section 503A(b)(1)(A).	recommend any changes to the proposed text. Staff note Staff note that should the Board accept the changes recommended by the commenter, the Board would compounding using a bulk drug substances that has been nominated for inclusion in 21 CFR section 216.23(a) and that

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			We also ask that the Board reconsider adding 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. Here too, we agree with the Board that pharmacists must be knowledgeable of current practice standards and legal requirements. However, our recommendation is focused squarely on the quality of the API used to compound drugs, which is an issue distinct from a pharmacist following practice standards to compound drugs. 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. **Recommended language revision:** 1736.9: "(e)(1) Except as provided in (2) or (4), when API is used to compound a CSP, it shall – (a) comply with a USP monograph; (b) if such a monograph does not exist, be an API that is a component of a drug approved by the FDA; or (c) 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	appears on the published 503A Category 1 bulk drug substances list. Staff further note that the Board has previously considered this comment. The Board respectfully refers the commenter to its prior response in row 21 available here, that includes, "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."

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			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	1736.17(a)(2)	Partnership For Safe Medicines	The Board's proposal to eliminate adverse event reporting requirements (sections 1735.11(a)(2), 1735.12(b), 1735.12(c), and 1736.17(a)(2)) presents severe risks, including: ● Delayed Detection of Drug Safety Issues: Without a diminished reporting system, it will take longer to identify harmful trends associated with specific medications. ● Reduced Transparency: Patients and healthcare providers will have less access to critical safety data that inform medical decision-making. ● Increased Harm from Compounded Medications: The absence of adverse event reporting will make it harder to promptly identify and respond to dangerous medications before widespread harm occurs. A Step Backward in Drug Safety California has historically been a leader in pharmaceutical regulation and patient protection. Removing adverse drug experience review would reverse this progress, making the state an outlier in drug safety oversight. Regulatory bodies, including the FDA and WHO, emphasize the necessity of adverse event monitoring as a fundamental component of a responsible healthcare system. The California Board Of Pharmacy should reject this proposed rule change and reiterate the responsibilities of compounders to have a standard operating procedure that requires	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the comment does not address modifications made in the third modified text. The Board's proposed compounding regulations are seeking to establish minimum requirements while relying on pharmacists to use their professional judgment. Board staff note that current law, Business and Professions Code section 4127.1(f) establishes mandatory reporting requirements to the Board including adverse effects reported or potentially attributable to a pharmacy's sterile drug product. This section also requires reporting to the MedWatch program. The Board shares the patient safety concerns raised by the commenter and believes the current statutory requirements remain appropriate.

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			mandatory reporting of all adverse events promptly.	