Martinez, Lori@DCA

From: Bob <bobgo1970@gmail.com>
Sent: Friday, February 21, 2025 10:57 AM
To: PharmacyRulemaking@DCA; Damoth, Debbie@DCA
Subject: Comments Re: proposed compounding regulations, after 2/16/15 mtg

Please confirm receipt of the following comments, to be applied to the current comment period on the proposed compounding regulations.

Issue #1:
The response by the Board that both proposed as well as existing regulations on compounding, as currently worded, do not infringe on the practice of compounding by non-pharmacist licensees under the jurisdiction of other California professional boards, is not satisfactory for the following reasons:
1. You responded with comments from only one board, the Medical Board of California, which only regulates MD's. This does not apply to other licensees such as DO's, nurses, ND's, dentists, and veterinarians, who may also have the right to compound medications in-office without a pharmacist and without interference by the Board of Pharmacy. Furthermore, even the MD's right to compound is still in jeopardy based on current wording of the Board's regulations, for the following reasons:
a. The Medical Board's letter noted that only the Medical Board has the right to discipline its licensees. This would only apply if the licensee was being disciplined as an MD, **not if they were being disciplined as a person practicing pharmacy without a license.** Again as previously stated, the Board of Pharmacy's jurisdiction is to regulate the practice of pharmacy, and therefore practicing pharmacy without a license would fall within their purview. Both currently existing regulations as well as the proposed changes exclude non-pharmacists from being able to compound, specifically **defining the practice of compounding as that which occurs by a pharmacist ONLY.** (See proposed regulation 1736.1a (a): "For the purposes of this article, sterile compounding occurs, by or under the direct supervision and control of a licensed pharmacist, pursuant to a patient specific prescription, unless otherwise specified in this article."
And see currently existing regulation:
CCR 1735(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist")
b): The Medical Board's letter notes: "It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding." - they admit that your regulations may affect MD's practice of compounding.

I'm not sure why you have so much resistance to adding wording which would only help to clarify the limitations of your role, and would limit the confusion and ambiguity which the current wording is creating. Instead, you have specifically chosen to include wording which is overly broad, and which implies that compounding only may be performed by a pharmacist.

2. You claim that regulations specifically state you cannot regulate other practitioners

3. Furthermore, you have not directly responded to previous comments that noted the contradiction between your stance on the above and the fact that you are currently making preparations to attempt to regulate what you refer to as

'IV hydration clinics'. These clinics do not have pharmacists, however they do have other non-pharmacist licensees who have the right to compound. The term 'IV hydration clinic' itself is not well-defined by the board, and it is foreseeable that the board could choose to include any medical office that provides IV hydration or IV nutrients in this category, offices in which compounding might be conducted by any of a variety of types of licensed non-pharmacist practitioners who should not be under the purview of the Board if it were not for the current language in your regulations. Therefore, the claim that your compounding regulations do not or will not interfere with compounding by non-pharmacist licensees in disingenuous. **Please do note and respond to this paragraph in full in your reply as well.'**

Given all of the above, I recommend you add the following or similar wording somewhere within Title 16 CCR:
"The regulations in Title 16 CCR Sections 1735 et seq,
1736 et seq, 1737 et seq, and 1738 et seq do not in any way apply to the practice of compounding by non-pharmacist licensees who have the right to compound based on their own practice act."

If however, you do want to have the ability to regulate non-pharmacist licensees, and are therefore unwilling to add the above language, it is imperative that you change all language in the current and proposed regulations that limit compounding to pharmacists alone - including the statement that compounding occurs by pharmacists only, and any language that requires you to have a pharmacist-in-charge in a facility that performs compounding.

Issue #2:
Given the BOP's previous claim in published administrative cases that the FDA requires the existence of a USP **DRUG** monograph in order to allow sterile compounding of any substance, not exempting 503a bulk drug category 1 substances, with the claim that the substance could not be determined to be pharmaceutical grade without such a monograph, I'd like you to explicitly clarify, by responding to this comment, whether the proposed regulations, as currently worded, would allow for the STERILE compounding of bulk drugs under the 503a bulk category 1 list, **EVEN IF THERE DOES NOT EXIST A USP DRUG MONOGRAPH for the substance** (though there might exist a non-US drug monograph OR a US dietary supplement monograph), **and as long as stability study requirements, quality testing requirements and proper compounding procedures as delineated in the BOP's regulations are met.**

Issue #3:
Question: On day one of the February 5th meeting, one of the board members stated that a 503b Outsourcing facility is able to make patient-specific medications. This is not consistent with what I have been told by the outsourcing facilities themselves, as well as by my medical peers. Can you please confirm if that board member's statement was correct?

Thank you.

Bob Go

CVSHealth

Mark Johnston, R.Ph
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2/14/25

California Board of Pharmacy,

I am writing to you in my capacity as Executive Director of Pharmacy Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points of care to patients in the state of California through our integrated offerings across the spectrum of pharmacy care that includes over 1,000 pharmacies located within California. We appreciate the opportunity to submit comments on the Board's pending compounding regulations.

CVS Health greatly appreciates the collaboration that has led to numerous changes in pending language throughout this promulgation, including 1735.15(b), which allows flavoring without a patient specific prescription. However, the language and methodology used to craft 1735.1(i) and 1735.15(a), which create two pathways for flavoring compliance, causes confusion and is not clear to the regulated community. The first pathway is to follow USP Chapter 795, FDCA section 503a, 1735.1 through 1735.14, and 1735.15(b), which I'll refer to as "pathway A". The second pathway is to follow 1735.14, 1735.15, USP Chapter 795, and FDCA section 503a, however a pharmacy cannot otherwise engage in nonsterile compounding in order to utilize this pathway, which I'll refer to as "pathway B".

Although pathway B has been billed as an exception, CVS Health believes that pathway B arguably establishes a greater mandate than just adhering to pathway A, as 1735.15(a)(5) requires a labeling mandate when flavoring while 1735.5 does not. Otherwise, 1735.1 through 1735.14 largely reiterate USP Chapter 795, and as 1735.15 also requires adherence to USP Chapter 795, it is questionable why pathway B exists. Pathway B would truly be an exception, if adherence to USP 795 was struck from 1735.15(a), as requested below.

Since it is unlikely community pharmacies will ease offering patients non-sterile compounding services in lieu of flavoring services exclusively, pathway B is not an option. Community pharmacies are simply highly unlikely to engage in flavoring if adherence to USP Chapter 795 is required. While there are several portions of USP Chapter 795 that we believe are too onerous without benefit to public safety to be applied to the act of flavoring a prescription, I'll offer one example. USP Chapter 795 requires gloves to be worn and the cleaning and sanitizing of the surfaces in the nonsterile compounding area on a regular basis or as specified in the USP.

CVS Health's request: pathway B not be tied to abstaining from engaging in nonsterile compounding and for pathway B to not require adherence with USP Chapter 795, as depicted below. Otherwise, community pharmacies will likely not be able to offer California patients flavoring, which deviates from the overwhelming majority of other states.

CVSHealth

1735.1. Introduction and Scope.

(i) A facility that ~~limits its compounding to~~ combine~~sing~~ a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of a prescriber, patient, or patient's agent shall be exempt from the requirements established in subdivision (f) and Sections 1735.2 – 1735.13. ~~A facility that performs any other form of nonsterile compounding at any time is not exempt as provided in this subdivision~~

1735.15. Flavoring Agents.

(a) ~~In addition to the standards in USP Chapter 795 and the Food Drug Cosmetic Act (FDCA) section 503a (21U.S.C. 353a) a~~ A facility that ~~limits its compounding~~ flavors as described in Section 1735.1(i) shall establish the following SOPs:

Sincerely,

Mark Johnston, R.Ph

Executive Director

Pharmacy Advocacy and Regulatory Affairs

CVS Health

Section, Subdivision	Proposed Language	Recommendation / Comment
Non-Sterile Compounding		
CCR 1735.d	(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, 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.	**Rationale:** We add our voice to others who commented on this section who pointed out their concern with the wording of this section. We appreciate the board's position that the intent is to rely on the professional judgement of the pharmacist. At the same time, we object to the wording of the regulation and wish to point out that this section has the potential to be misinterpreted as written, both currently and in the future. It is important to get this right so that the intent is clear and does not cause confusion. The wording of ""Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product," could be interpreted to mean that ANY compound being made is defined as essentially a copy of a commercially available drug product. The trouble here is that any compounded drug that has the same API as a commercially available drug product will violate this regulation. Using the example of a hospital pharmacy that compounds 10 bags of Oxytocin 30 Units in 500ml Normal Saline for use in their Labor and Delivery (L&D) unit. The Oxytocin bag is made by using three 1ml vials of Oxytocin 10units/1ml. By the definition above, it will be a violation of this proposed regulation since these bags are made in bulk and they include the same API as the commercially available drug product of Oxytocin 1ml. These bags are made in bulk, so, by definition, it is not being compounded specifically for an identified individual patient that produces for that patient a clinically significant difference. These bags are being used for almost every patient that will have a delivery on the unit, so one cannot argue that it is being made for a specific individual patient. This proposed regulation, if it is read simply for the way it is stated, will imply that the pharmacist verifying the order will need to go through a process of verifying with the prescriber and then documenting each and every order for Oxytocin bags that the change from the commercially available 10 unit per 1ml vial to a compounded 30 unit per 500ml Oxytocin bag produces a clinically significant difference for each individual patient. In the ISOR, the board states that the FDA guidance document is being utilized to provide guidance regarding this definition (ISOR section copied herewith for reference):

		New subdivision (d) adds the definition of "Essentially a copy." A definition is in current section 1735.1(k) of the board's regulations. It is retained and moved into this definitions section of the new language as it is not included within USP <795> and is used elsewhere in the proposed regulations. The board, however, amended the existing language slightly to provide additional clarity and consistency by amending "comparable" to the "same" active pharmaceutical ingredients (APIs). This change is necessary to align the definition with the FDA guidance document, which says "the compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product." (This FDA guidance document is available as underlying data of this rulemaking; see item number 9 in the Underlying Data section of this document.) Further, this definition ensures that the pharmacist can use their professional judgment when determining if a compound is essentially a copy. Pharmacists must remain knowledgeable of current practice standards and legal requirements for the profession when exercising their professional judgment. It is important to note that the definition taken from the FDA guidance document and used in this proposed regulation, is only one part of three of the definition in the guidance document. Herewith the guidance document section on "Essentially a Copy" for reference: FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if: • the compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product; • the API(s) have the same, similar, or an easily substitutable dosage strength; and • the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug, unless, as provided by section 503A(b)(2), a prescriber determines that there is a change, made for an identified individual patient, which produces, for that patient, a significant difference from the commercially available drug product. The proposed regulation definition crucially leaves out the requirements for a same or similar dosage strength and route. By leaving out these clarifying terms, the definition is now so broad that it is inclusive of every single non-sterile and sterile compound being compounded by a pharmacy in the state of California. From our example above, it is open to interpretation by both the regulated public and board staff of what "essentially

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

1735.12(b)	(b) The Board shall be notified in writing within ~~72~~ 96 hours of the facility's receipt of a complaint of a potential quality problem ~~**or the occurrence of an adverse drug experience as defined in 21 CFR 310.305(b)** drug event~~ involving a CNSP.	**Rationale:** The way that this regulation is worded could be misinterpreted. This proposed regulation was discussed by the board during the last board meeting, and it was mentioned that the intent is for complaints that indicate true quality problems be reported to the board. From the way that it is written, the understanding that one could derive from the language is that the board must be notified of all complaints that could potentially indicate a quality problem. For example, a patient given a compounded gel, could complain that from their recollection it appears to have a slightly different opacity from one dispensed previously. Since this could potentially indicate a quality problem, the pharmacist will then report the complaint of a potential quality problem to the board. The pharmacist then investigates and finds that the medication was compounded correctly but the master formula was changed to a different gel base due to a change in manufacturers. One of members reported to CSHP that they started to report all complaints that could indicate a potential complaint to the board. They were instructed by board staff that they should only report it when there was an actual quality problem since they were inundating the board with reports. It shows that there has been confusion with the current regulations. It is important that we use this opportunity to make the language as clear as possible. While all involved currently in the creation and comments may have a grasp and understanding of the intent of this proposed regulation, we must take the multiple comments from all stakeholders as an indicator that there will be future misunderstanding and misinterpretations of this language. It is of the utmost importance to recognize that ten to fifteen years from now these interpretations and intent will be forgotten, and the only guidance left to enforce are the words as written. We are sure that the current board would not want future board members and staff to enforce this rule under the misunderstandings that we and others took great pains to point out at this moment in time. **Recommendation:**

		(b) The pharmacy shall report in writing a product quality issue for any compounded product to the board within 96 hours after the pharmacy receives notice of the product quality issue.
Sterile Compounding		
CCR 1736(e)	(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, 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.	**Rationale:** We add our voice to others who commented on this section who pointed out their concern with the wording of this section. We appreciate the board's position that the intent is to rely on the professional judgement of the pharmacist. At the same time, we object to the wording of the regulation and wish to point out that this section has the potential to be misinterpreted as written, both currently and in the future. It is important to get this right so that the intent is clear and does not cause confusion. The wording of ""Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product," could be interpreted to mean that ANY compound being made is defined as essentially a copy of a commercially available drug product. The trouble here is that any compounded drug that has the same API as a commercially available drug product will violate this regulation. Using the example of a hospital pharmacy that compounds 10 bags of Oxytocin 30 Units in 500ml Normal Saline for use in their Labor and Delivery (L&D) unit. The Oxytocin bag is made by using three 1ml vials of Oxytocin 10units/1ml. By the definition above, it will be a violation of this proposed regulation since these bags are made in bulk and they include the same API as the commercially available drug product of Oxytocin 1ml. These bags are made in bulk, so, by definition, it is not being compounded specifically for an identified individual patient that produces for that patient a clinically significant difference. These bags are being used for almost every patient that will have a delivery on the unit, so one cannot argue that it is being made for a specific individual patient. This proposed regulation, if it is read simply for the way it is stated, will imply that the pharmacist verifying the order will need to go through a process of verifying with the prescriber and then documenting each and every order for Oxytocin bags that the change from the commercially available 10 unit per 1ml vial to a compounded 30 unit per 500ml Oxytocin bag produces a clinically significant difference for each individual patient.

		In the ISOR, the board states that the FDA guidance document is being utilized to provide guidance regarding this definition (ISOR section copied herewith for reference): New subdivision (d) adds the definition of "Essentially a copy." A definition is in current section 1735.1(k) of the board's regulations. It is retained and moved into this definitions section of the new language as it is not included within USP <795> and is used elsewhere in the proposed regulations. The board, however, amended the existing language slightly to provide additional clarity and consistency by amending "comparable" to the "same" active pharmaceutical ingredients (APIs). This change is necessary to align the definition with the FDA guidance document, which says "the compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product." (This FDA guidance document is available as underlying data of this rulemaking; see item number 9 in the Underlying Data section of this document.) Further, this definition ensures that the pharmacist can use their professional judgment when determining if a compound is essentially a copy. Pharmacists must remain knowledgeable of current practice standards and legal requirements for the profession when exercising their professional judgment. It is important to note that the definition taken from the FDA guidance document and used in this proposed regulation, is only one part of three of the definition in the guidance document. Herewith the guidance document section on "Essentially a Copy" for reference: FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if: • the compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product; • the API(s) have the same, similar, or an easily substitutable dosage strength; and • the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug, unless, as provided by section 503A(b)(2), a prescriber determines that there is a change, made for an identified individual patient, which produces, for that patient, a significant difference from the commercially available drug product. The proposed regulation definition crucially leaves out the requirements for a same or similar dosage strength and route. By leaving out these clarifying terms, the definition is now so broad that it is inclusive of every single non-sterile and sterile compound being

		compounded by a pharmacy in the state of California. From our example above, it is open to interpretation by both the regulated public and board staff of what "essentially a copy" is because it will be everything with the same API. By the proposed definition, since diazepam tablets are commercially available, a pharmacy may not compound a diazepam drip from IV vials since the tablets 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 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.
CCR 1736.1 Introduction and Scope. Subsection (b):	(b) (1) Except as allowed in paragraph (2),CSPs for direct and immediate administration as provided in the Chapter shall only be compounded in those limited situations where the failure to administer such CSP could result in loss of life or intense suffering of an identifiable patient. Any such compounding shall be only in such quantity as is necessary to meet the immediate need of the patient. If not already documented in the patient's medical record, documentation for each such CSP shall also include, the compounded date and time, the patient's name and patient's unique identifier and the circumstance causing the immediate need of the patient. Such documentation need not be redocumented by the compounding staff if already available. (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 used for 48 hours after such failure(s). All such failures must be documented in accordance with	**Rationale:** 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 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

	facility's SOP and shall be reported to the Board within 72 hours. (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 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.	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 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. 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 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 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 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. 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. 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.
1736.1.(e)	(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, unless: (A) the 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 or **within 60 days of the end of the shortage and ~~at the time of dispensing~~**, or **in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug**	**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.

	product cannot be obtained from the manufacturer or wholesaler and documentation is maintained, or (B) The pharmacist ~~**determines**~~ **verifies** and documents that the compounding produces a clinically significant difference for the medical need of an identified individual patient. (C) Documentation describing the conditions in (1)(A) **and** (1)(B) is maintained in a readily retrievable format.	**Recommendations:** 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.
Hazardous drugs		
CCR 1737.7. Personal Protective Equipment (PPE), subsection (c).	(c) Outer gloves used for HD compounding shall be changed between each different HD preparation, unless preparing multiple HD preparations of the same drug or preparing multiple HD preparations for a single patient.	**Rationale:** We re-state our separate recommendations as before since the board failed to include either an explanation of how each objection or recommendation of the proposed action has been changed to accommodate our comment or state the reasons for rejecting our comments. In summarizing and responding to our comments, the board did not demonstrate that it understood and considered the comment in that board did not demonstrate that it understood and considered the comment the risk to staff created via repeated change of outer gloves. Double-gloving is primarily designed to offer extra protection against hazardous drug compounds, with the outer glove serving as a first line of defense. If the outer glove is repeatedly removed or exposed to rough conditions, it may wear down, possibly increasing the risk of puncturing, drug permeation, or compromising the inner glove. This could lead to reduced protection and potential occupational exposure, especially when handling hazardous drug compound. We recommend that the regulation section be deleted since consideration was not given for the risk to staff. The board did not demonstrate that it understood and considered the comment regarding the inappropriateness of the use of online prices for gloves. Since the board is unable to justify its use of internet pricing, we recommend that the regulation be deleted due to inadequate economic impact analysis. The glove prices that board staff looked up online is not available to all pharmacies due to limitations on contracting. Board staff's response that they performed an online search of the pricing and

		availability of appropriate gloves reflects a lack of understanding of the practice of pharmacy and the intricacies of purchasing contracts at large organizations. Pharmacies cannot simply go to any online vendor of these sterile gloves and buy it on a credit card. Purchasing is usually done on contracts with vetted suppliers to ensure supply chain integrity. Due to this workflow, the pricing advertised online from unvetted suppliers, is generally unavailable to organizations. Furthermore, the cheapest online price may not reflect the product that is selected for use by the pharmacy since there are factors to be considered such as ease of use, quality of the product and in some cases, impact on staff that could experience allergic skin reactions to cheap products. We would like to request that the board make public their source of information and the brand name, type and quality of the gloves they found online. Reports from CSHP members indicate that the price for a pair of high quality sterile hazardous drug gloves on contract is $1.30. Assuming that a staff member works 10 hours per day in a biological safety cabinet, they will have to replace gloves every 30 minutes (which is 20 times). This is an additional cost of $26 per day, which translates to $130 per week and $6,760 annually. This is the presumptive cost per biological safety cabinet (BSC) for the price of gloves alone. It is also anticipated that the exchange of gloves will translate to a minimum of 10% reduction in productivity. This means for every 30 drugs being compounded per day, there is now 3 less. This means at least one patient per day per BSC cannot be accommodated in an infusion center, with a resulting decreased patient access to care. The charges for 3 drugs can range between $1000 up $30,000, depending on the drugs. This translates in an economic impact of loss of revenue of up to $30,000 per day. Even a low estimate of $2000 per infusion day translates to $520,000 loss off revenue per year per BSC. Even an unrealistic loss of revenue of $500 per day translates to a loss of $130,000 per BSC per year due to lost productivity. This economic impact on the exchange of sterile gloves alone far exceeds the total estimates of the economic impact provided by the board for all of the compounding regulations combined. Due to gross underestimation of the board of the impact of glove exchanges alone, we recommend that this section be deleted. The board did not demonstrate that it understood and considered the comment regarding the need to purchase gloves at increased prices for staff that are allergic to cheap gloves. Due to the non-universal application of the use of cheap gloves, we recommend that this regulation be deleted. The board did not demonstrate that it understood and considered the comment regarding the fact that this economic impact was inadequately addressed in the

		economic impact section of the ISOR. The board response regarding the price of gloves highlights board staff's limited understanding of pharmacy business. The one-dimensional view of product price as an economic impact fails to consider indirect costs associated with this proposed regulation such as increased time it will take to compound hazardous drugs and the associated cost of labor. It further fails to consider the economic impact of slower compounding on reduced turnover in chairs at infusion centers. These are only to name a few economic impacts that the board fails to take into consideration and illustrates our point that the board lacks the internal expertise to accurately reflect those anticipated costs.. Given the information is not available, we recommend that this regulation be deleted. We once more are compelled to note that, as with other proposed regulations, the "business impact" and "economic impact" of the ISOR fails to accurately reflect the cost and impact to businesses by this and other regulations. The board's response to the question of "Business Impact" in the Initial Statement Of Reasons (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, increased purchase of PPE, increased testing and enhanced reporting requirements. The amount stated is a gross underestimation of the true cost to health systems. Understandably the Board lacks the internal expertise to accurately reflect those anticipated costs associated with development of policies and procedures, monitoring implementation of those procedures, correctly reporting to the Board as proposed by this regulation and others, cost of monitoring visits by the Board, 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." For these reasons, we recommend that this regulation be deleted.

February 20, 2025

Anne Sodegren, Executive Officer
Seung Oh, President
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Dear President Oh, Director Sodegren, and Members of the California State Board of Pharmacy:

Eli Lilly and Company ("Lilly") respectfully offers these comments in support of the Third Modified Regulation Text of the Notice of Proposed Regulatory Action Concerning: Compounded Drug Products issued by the California State Board of Pharmacy (the "Board").

Lilly is a medicine company turning science into healing to make life better for people around the world. We have been pioneering life-changing discoveries for nearly 150 years, and today, our medicines help more than 51 million people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges. In 2024, Lilly spent over $10.9 billion on research and development, conducting clinical research in more than 50 countries.

We recognize the Board's proposed regulatory changes are in their 3rd phase of revision and near finalization. We thus have chosen to limit our comments to what has changed since a previous version – notably the language edit in draft Article 4.5, Sec. 1735(d) and 1736(e) revised from "*determined* and documented by the pharmacist" to "*verified* and documented by the pharmacist" (emphasis added). This comment does not reflect the entirety of Lilly's views on compounding. Lilly looks forward to sharing additional feedback in other forums.

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. As the Board is aware, compounded drugs should only be used in patients whose identified medical needs cannot be met by an FDA-approved medicine. FDA-approved medicines are exhaustively studied, identified to FDA, made in facilities registered with FDA, inspected by FDA for compliance with current good manufacturing practice (cGMP) prior to being introduced to the U.S. market, and ultimately determined by FDA to be safe and effective for their intended uses. After approval, manufacturers often are required to conduct additional studies of their medicines and they must always report all adverse events. They also must track and trace every finished unit to help protect patients from counterfeit or illegitimate products. And they generally must not employ individuals who have been convicted of crimes related to the regulation of drug products.

None of those critical public health protections apply to drugs produced by compounding pharmacies. Unnecessary use of compounded drugs may expose patients to potentially serious health risks. For example, between August and October 2024, FDA and California authorities inspected a compounding pharmacy known as Fullerton Wellness. The authorities concluded that "Fullerton Wellness used non-sterile ingredients to make these injectable drugs and took no steps to sterilize them." FDA, FDA warns patients and health care professionals not to use compounded drugs from Fullerton Wellness (Nov. 1, 2024), https://tinyurl.com/ybub6ppm. FDA therefore warned doctors to "immediately check their medical supplies, quarantine any drug products from Fullerton Wellness, and not administer them." *Id.* FDA further cautioned patients to stop using drugs made by Fullerton Wellness. *Id.* The Fullerton example is just one of countless public safety incidents caused by unapproved drugs made by compounding pharmacies.

The "essentially a copy" ("EAC") prohibition is one of the key legal prohibitions that prevents compounding pharmacies from selling knockoffs of FDA-approved medicines. For it to serve its intended purpose (which is to prevent end runs around the new drug approval requirement in the guise of compounding), the EAC prohibition must be broad and must not be easily evaded. To that end, Lilly offers the following comments. :

1. We applaud the Board's proposal to define "essentially a copy" to include any compounded drug "that includes the same active pharmaceutical ingredient(s) (API(s))" as an approved medicine. This broad definition will ensure that the EAC prohibition protects the public health as it was intended by ensuring that compounding pharmacies cannot evade the prohibition through minor or pretextual formulation changes.

2. We also applaud the Board's proposal to limit the exception to the EAC prohibition to situations where the pharmacist has "verified and documented" that the compounded drug will produce a "clinically significant difference" for the specific patient. This verification also is essential to protect the public health and prevent evasion. All too often, providers and pharmacists (often working together pursuant to contracted commercial arrangements) have attempted to evade the EAC prohibition through sham prescriptions and other illicit measures. Requiring the pharmacist to use his or her professional judgment to verify that the compounded drug makes a *real* change that will be clinically significant will help to ensure that patients receive FDA-approved medicines whenever possible.

Thank you for considering our comment.

Sincerely,

Fielding Greaves
Senior Director, State Government Affairs
Eli Lilly and Company

Comments of Eli Lilly and Company Regarding the Notice of Proposed Regulatory Action
Concerning: Compounded Drug Product

Section, Subdivision	**Proposed Language**	**Recommendation / Comment**
1735(d) & 1736(e)	(e) "Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product, except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as ~~**determined**~~ **verified and documented** by the **pharmacist** ~~**prescribing practitioner**~~, between that compounded preparation and the comparable commercially available drug product.	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.

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Dr. Seung Oh
President
California State Board of Pharmacy
2720 Gateway Oaks Dr., Ste 100
Sacramento, CA 95833

February 19, 2025

President Oh and Members of the California State Board of Pharmacy,

If the intention of the Board is to bring medication flavoring back to California's pharmacies and families, which you've indicated it is, then the language you are considering for approval will not accomplish that. The caveat language in 1735.1 (i), which ties the regulation of flavoring to other pharmacy activities, is the problem. Tethering flavoring to totally unrelated products or services offered in the pharmacy will prevent pharmacies from reintroducing the service. This is not speculation. Pharmacy owners and operators have told you this point blank. I have heard this consistently from our pharmacy partners as well. The good news is, the fix is easy. Allow the exemptions afforded in 1735.15 to stand alone. Let flavoring be regulated as flavoring, regardless of other activities a pharmacy performs.

I have provided my official comments below in the requested format.

Regards,

Chad Baker
Senior Vice President, Government Relations
FLAVORx, Inc.
cbaker@flavorx.com

Institution/Contact Name	FLAVORx/Chad Baker	
Section, Subdivision	**Proposed Language**	**Recommendation/Comment**
1735.1, Introduction & Scope.	**(i) A facility that limits its compounding to combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of a prescriber, patient, or patient's agent shall be exempt from the requirements established in subdivision (f) and Sections 1735.2 – 1735.13. A facility that performs any other form of nonsterile compounding at any time is not exempt as provided in this subdivision.**	The caveats highlighted in this text make no sense. Why is the sole act of flavoring FDA approved liquid medications being tied to other, totally unrelated activities in the pharmacy? What does producing a Magic Mouthwash solution for a chemotherapy patient have to do with flavoring an amoxicillin prescription for a child with strep throat? Why can't pharmacies that choose to flavor just abide by the provisions in 1735.15 and leave it at that? The Board itself appears confused and confounded by this language as well, as evidenced by comments from Member Sandhu at the January 8 meeting and Chair Oh and Member Crowley at the February 5 meeting. **The practical implication of approving the language as is will be to perpetuate the freeze on pharmacies offering flavoring to their customers**. The pharmacies I've spoken with would like to start flavoring again AND continue to provide basic non-sterile compounding to their customers. But these same pharmacies have indicated clearly, in both their words and actions, that they cannot and will not have flavoring regulated the same as, for example, preparing Magic Mouthwash. You are forcing

		them to pick and choose with this language, which is not in any way beneficial to consumers. If the Board is OK with the exemptions for flavoring that are provided in 1735.15, then it should be OK with them in all cases, independent of what other services the pharmacy provides. Here's the easy fix: "A facility that compounds using flavoring agents combined with a prescribed FDA approved drug in an oral liquid dosage form at the request of a prescriber, patient or patient's agent shall be exempt from the requirements established in subdivision (f) and Sections 1735.2 – 1735.13." Plain. Simple. No caveats. You have made great progress with the exemptions contained in 1735.15. Please don't make it all for naught.

KSG.PharmD, Pharmacist Consultant, Inc.

A Professional Corporation

2025.12.11

To: The California Board of Pharmacy

Re: Title 16 Third Modified Text. of proposed regulation for compounding

I provide these comments as a Compounding Pharmacist who has been compounding custom medications for patients' needs for over 40 years. Additionally, I offer the insights and expertise augmented by my master's degree in Pharmaceutical Outcomes Policy. It is my goal to promote patient safety, while preserving the heritage and art of compounding within the profession of pharmacy. *Secundum Artem*

I will limit my comments to non-sterile compounding (USP 975) and non-sterile hazardous drug compounding (UAP 800) since, other than a short time in hospital admixture preparation, I have no experience in sterile compounding.

In my first public comment, I criticized the Board for duplicating much of what was already published by the United States Pharmacopeia (USP), and adding costly extra, and, in my opinion, unnecessarily complicating processes that did not appear to add to patient protections. Though not perfect I must complement the Board for taking into consideration the large number of public comments it received and crafting a much better, more concise set of regulations. But I will comment on some items I feel are unnecessary or need further clarification. And as a general rule I will always ask for evidence-based justification for any new or change in regulation above and beyond the expertise of the USP which has been the definitive medicine quality guidelines since 1820.

I will remind the Board that any and all complications to compounding regulations increased labor hours, or materials costs subsequently increase the cost to the patient. I am sure it is not the Board's intent to unnecessarily impede patient access to medications due to higher costs that do not support the Board's prime directive of consumer (patient) protections.

1735.1(d)(2): What is the purpose for restricting veterinarian office use medications to 14 days? There is no reason why veterinarians should not be afforded the same office use parameters as human practitioners under CCR 1735.2[c][1], sub section [3] seems to imply that veterinarians are a lesser class of prescriber.

1735.1[e][1][a]. How long must the documentation of drug shortage be retained?

1735.1[e][1][c]. *ibid*

1735.2[c]. How long must this documentation be retained?

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1735.4[b]. please define "high quality water". Is any municipal water supply high quality?

1735.5[a]. The cleaning and sanitizing supplies used are stated in the Policy and Procedure manual. It is unnecessary to record this information daily and only adds to costs without adding to patient safety.

1735.6[a]. Compounding is an art form. Techniques, tools, and equipment are subject to being used in new and unique ways to achieve a product that a patient can use/tolerate. From a patient outcomes view, restricting equipment use to manufactures specifications inhibits innovation that

can result in good patient outcomes. It is my opinion this section should be eliminated. The sole purpose of compounding is to adopt existing drugs to a specific patients' needs.

1735.8[A]. Including the dispensing pharmacist as being responsible for the integrity, strength, quality, and labeled strength places undue liability on the dispensing pharmacist who may not have been on duty when the CNSP was compounded; therefor has no process other than the compounding record to base that decision on; a compounding record that was already checked and approved by another licensed pharmacist. The "dispensing pharmacist" should be eliminated, and limited to the pharmacist that made, or signed off on the compound.

1735.12[b]. The Board is asking to be inundated with unnecessary paperwork to evaluate. There are many reasons a patient might complain about a compounded product: flavor, texture, dosage form preference, *etc.* ONLY VALIDATED complaints regarding integrity, strength, and quality should be reported to the board. The board does not to spend time and money investigating complaints of flavors, or texture, or even a complaint about strength IF the pharmacy sends the product in question for testing and the product results are within specifications. Respectfully, the board made this mistake already with the reporting ANY loss of controlled substance found during the controlled substances reconciliation.

1737.5. Please validate the augmentation above USP 800 to certify C-PEC's every 6 months over the annual certification codified in USP 800.

1737.6. The Board wants to codify a wish, a suggestion, an idea for environmental sampling, then goes on to state this sampling is not required. Considerations, and suggestions best left to professional organizations who develop "best practice" models. They do not belong in codified law. Strike this section.

1737.16. Spill control is already addressed in USP 800. It is unnecessary for the Board to restate the need for spill control SOP.

This concludes my comments for the third modified text. As I said above, this is a great improvement over the original proposal, and I thank the Board, for taking so many public comments under consideration to refine the third modified text proposal

Warm Regards

K. Scott Guess, PharmD, MS Pharm. RPh, APh

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Institution /Contact Name	Sutter Health Melanie Horn, Pharm D, BCSCP	
Section, Subdivision	**Proposed Language**	**Recommendation / Comment**
1735 (e)	Board Proposed Third Text: (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….** **Proposed Based on FDA definition with 503A :** "Essentially a copy" of a commercially available drug product means a preparation that includes 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. Compounding "Essentially a copy" of a commercially available drug product is not the compounding of finished drug products (or conventionally manufactured sterile component) but **compounded using bulk drug substance(s), as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations.**	The recommendation reiterates concerns about California's definition of "essential copy" in hopes of further providing detail of the broad definition and the impact. The Board aims to align with the federal 503A standard, but the nonspecific definition lends to comprehensive noncompliance and does not capture the compounding activities which the Board intends to take regulatory action on. According to section 207.3(a)(4) of title 21 of the Code of Federal Regulations, compounding "essentially a copy" involves using bulk drug substances (APIs), not finished drug products. The current and proposed California definitions exceed federal 503A exemptions, especially within healthcare facilities, creating compliance issues. In a medium to large California hospital, compounding pharmacies prepare over 1,000 patient-specific compounds daily under USP 797 standards. These compounds, sharing APIs with commercial products, are deemed "essential copies" under California's restrictive code, requiring extensive documentation for each patient, which is impractical and not the intent of the Board to regulate the activities within scope of the existing and proposed definition. The California Board's definition does not align with FDA's 503A exemption, which allows professional judgment. The state's definition demands documentation of clinical differences for every compound, unlike the federal standard. Examples of discrepancies include: 1. **Vancomycin oral solution (DIFICID) for C. difficile treatment, vancomycin lyophilized sterile powder vials, and vancomycin premix IVPB Xellia bags with PEG** all share the same API. Compounding a weight-based IVPB for surgical prophylaxis in orthopedic surgery the day prior to anticipated need for intravenous therapy is compounding an essential copy under the CA definition but not under the FDA. 2. **Cefazolin oral suspension (FDA-approved dosage form)** shares the same API as cefazolin 2-gram sterile lyophilized powder. 3. **Vasopressin premix bags of IV solution and the FDA-approved vials of vasopressin solution** with an FDA-approved package insert that details making an IV infusion is compounding an essential copy. 4. **Creating clonidine oral suspension compound for a neonate** shares the same API as clonidine tablets. 5. **Repackaging a Zosyn premix IVPB product**

		into a syringe to administer to a neonate is defined in CA as an essential copy. 6. **Compounding Daptomycin lyophilized powder sterile vial** to compound rather than the Baxter premix Daptomycin vial. The California Board should adopt either the FDA's definition or clarify the specificity of API/bulk drug substance compounding to provide clear expectations and enforcement standards to support the necessary compounding practices. The current regulation is impractical and burdensome, forcing hospitals to violate the law, lack clarity or over-document. Updating the definition to reflect safe, practical compounding under the federal 503A exemption is essential. Let's establish a meaningful, enforceable standard.
1736.1. (2)	(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 used for 120 hours after such failure(s). All such failures must be documented in accordance with facility's SOP and shall be reported to the BOP Board within 72 hours.** ~~**(3) If the sterile compounding equipment or environment fail(s) to meet any required specification in a hospital without alternative compounding area(s) onsite 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 shall be reported to the Board within 72 hours.**~~	**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. While larger facilities may have alternative compounding locations, as discussed during the Board Committee's discussion of this allowance, onsite compounding with shorter beyond-use dates for immediate use is much preferred over offsite compounding and shipment. There is no determination that critical 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, pharmacy-driven immediate use program and reporting to the Board. Please do not create differing standards for critical access versus other health care facilities when, across the nation and within all other non-pharmacy care settings, immediate use is an allowable federal standard of practice with aseptic training and 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 or secondary compounding area onsite.
1736.2. Personnel Training and Evaluation	(d) Compounding personnel or persons with direct oversight supervision and control over of compounding personnel who on **initial competency** fail any aspect of the aseptic manipulation ~~ongoing~~ training and competency evaluation shall not be involved in compounding or oversight of the preparation of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. Compounding personnel or persons with direct oversight supervision and control over of compounding personnel who on fail any aspect of the aseptic manipulation **ongoing** training and competency evaluation **[based on investigation of the failure determined poor aseptic practices]** shall not be involved	**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).

	in compounding or oversight of the preparation of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. A person with only direct supervision and control of personnel who fails any aspect of the aseptic manipulation **ongoing** training and competency evaluation may continue to provide only direct supervision and control of personnel for no more than 30 days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending.	**Observation Over growth:** 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.

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February 20, 2025

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste 100
Sacramento, CA 95834

Submitted via electronic mail to: Lori Martinez, California State Board of Pharmacy

RE: ***Compounded Drug Products Regulations***

Dear Ms. Martinez:

Kaiser Permanente appreciates the opportunity to respond to the California Board of Pharmacy's request for comments on the proposed regulations addressing nonsterile compounding, sterile compounding, and hazardous drugs. Kaiser Permanente comprises the non-profit Kaiser Foundation Health Plan, the non-profit Kaiser Foundation Hospitals; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan. These entities work together seamlessly to meet the health needs of Kaiser Permanente's nine million members in California. Kaiser Permanente's pharmacy enterprise in California is comprised of hundreds of licensed pharmacies that are staffed by thousands of individual pharmacy licentiates. The frontmatter of this letter comprises our general comments on the entirety of the proposed regulations; our comments on specific elements of the regulations are in the table that follows (in the table, Kaiser Permanente's proposed changes are denoted in red font with a strikethrough for deletions).

The process of developing the new USP compounding chapters spanned more than 10 years with rigorous review of current scientific evidence and more than 10,000 public comments.[1] The end result was the updated USP compounding chapters, which were designed to provide comprehensive evidence-based best practices for the compounding of all compounded drug preparations in all compounding environments. Throughout the rulemaking process, the Board has assumed that adding what it views to be omissions from the USP compounding chapters to its own regulations will improve the safety of compounding and compounded products for California consumers. This is a faulty assumption; in fact, excessive regulations in healthcare, particularly those not supported by empirical evidence, can significantly increase complexity in the healthcare system and lead to an increased risk of errors. According to the American Hospital Association, regulatory overload not only raises costs to the healthcare system but also reduces the time healthcare professionals can dedicate to direct patient care, thereby increasing the likelihood of errors.[2] As such, we believe that the Board's decision to promulgate additional requirements on top of the USP standards, particularly regulations without supporting evidence, will increase the complexity that pharmacy licensees must navigate and is just as likely to introduce new sources of error as it is to protect California patients. Given these factors, Kaiser Permanente continues to support the following alternative approach:

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[1] Alana Hippensteele, *USP Expert Discusses Revisions to Compounding Chapters <795>, <797>*, Pharmacy Times (Nov. 18, 2022), https://www.pharmacytimes.com/view/usp-expert-discusses-revisions-to-compounding-chapters-795-797-.

[2] American Hospital Association, Regulatory Overload Report, https://www.aha.org/guidesreports/2017-11-03-regulatory-overload-report?form=MG0AV3 (last visited Feb. 20, 2025).

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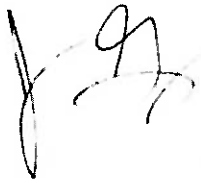
1. The Board should accept the proposal to repeal sections 1708.3. 1708.4, and 1708.5 of Title 16, Division 17, Article 2 of the California Code of Regulations and to repeal 1735 et seq of Title 16, Division 17, Article 4.5 of the California Code of Regulations and to repeal 1751 et seq of Title 16, Division 17, Article 7 of the California Code of Regulations.
2. The Board should reject the proposal to add new sections 1735 et seq of Title 16, Division 17, Article 4.5 of the California Code of Regulations, and to add new sections/Article 1736 et seq of Title 16, Division 17, Article 4.6 of the California Code of Regulations, and to add new sections/Article 1737 et seq of Title 16, Division 17, Article 4.7 of the California Code of Regulations, and to add new sections/Article 1738 et seq of Title 16, Division 17, Article 4.8 of the California Code of Regulations.
3. The Board should enforce the provisions of the USP compounding chapters as required by California Business and Professions Code section 4126.8.

If the Board elects to finalize the proposed regulations, we continue to encourage the Board to establish a rational effective date for these regulations that will provide the regulated public with ample time to come into compliance with these new requirements. Given the nature of the changes that have been made during previous public comment periods, we believe that a period of nine months—rather than the one-year period we were previously requesting—from the date that the regulation is filed with the Secretary of State would be a reasonable effective date. If the proposed regulation is finalized as written, Kaiser Permanente will need to make extensive updates to our policies and standard operating procedures and enhancements to our pharmacy information systems. These tasks are time-consuming, costly, or both and, as such, the Board should establish a delayed effective date for organizations to do the work needed to meet these requirements.

Kaiser Permanente appreciates the opportunity to provide feedback in response to the proposed regulations addressing nonsterile compounding, sterile compounding, and hazardous drugs. If you have questions, please contact John Gray (562.417.6417; john.p.gray@kp.org) or Rebecca Cupp (562.302.3217; rebecca.l.cupp@kp.org).

Respectfully,



John P. Gray, PharmD, MSL
Director, National Pharmacy Legislative and Regulatory Affairs
Kaiser Permanente

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Section, Subdivision	Proposed Language	Recommendation/Comment
Article 4.5 Nonsterile Compounding		
Article 4.6 Sterile Compounding		
1736.1(b)	~~(b) (1) Except as allowed in paragraph (2), CSPs for direct and immediate administration as provided in USP Chapter 797 shall only be compounded in those limited situations where the failure to administer such CSP could result in loss of life or intense suffering of an identifiable patient. Any such compounding shall be only in such quantity as is necessary to meet the immediate need of the patient. If not already documented in the patient's medical record, documentation for each such CSP shall also include the compounded date and time, the patient's name and patient's unique identifier and the circumstance causing the immediate need of the patient. Such documentation need not be redocumented by the compounding staff if already available.~~ ~~(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 used for 48 hours after such failure(s). All such failures must be documented in accordance with facility's SOP and shall be reported to the Board within 72 hours.~~	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 regulation that will achieve that result. If, instead, it is the Board's intent to incentivize immediate use compounding by pharmacy personnel who complete extensive 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.
Article 4.7 Hazardous Drugs		
1737.7(c)	~~Outer gloves used for HD compounding shall be changed between each different HD preparation, unless preparing~~	In attempting to impose the requirement that compounding personnel change their outer HD gloves after each different HD

[3] California Board of Pharmacy, Staff Recommended Response to Comments – Section 1736 et seq, https://www.pharmacy.ca.gov/meetings/agendas/2025/25_feb_bd_mat_1736_comments.pdf (last visited Feb. 20, 2025).

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	~~multiple HD preparations of the same drug or preparing multiple HD preparations for a single patient.~~	preparation or each different patient, the Board is proposing a regulation that will increase the risk of microbial contamination and is likely to increase the risk of medication errors with no evidence to support the contention that the practice will reduce the risk of contamination with HD residues. In our comment letter dated January 24, 2025, we demonstrated that, based on probability and peer-reviewed literature, increasing the frequency of glove changes will increase the risk of microbial contamination due to inevitable breaks in technique during the garbing process. The Board's response to this feedback was that "facilities can develop strategies to mitigate those risks."[4] This response fails to recognize that humans are fallible and, as such, even with the best mitigation strategies, occasional breaks in technique are inevitable to occur and create the opportunity for contamination. Therefore, it is indisputable that mandating more frequent glove changes will increase the risk of microbial contamination. The proposed regulation indicates that the outer HD gloves must be changed "between each different HD preparation unless preparing multiple HD preparations of the same drug or preparing multiple HD preparations for a single patient." This will almost certainly incentivize pharmacies to compound preparations of the same HD in "batches." Such an approach to compounding could result in several preparations of the same drug for different patients in the compounding area at the same time—an error-prone practice. The Board has provided two references to support this proposed regulation. First, in the Modified Initial Statement of Reasons the Board claims that "ASHP guidance" supports the notion that outer HD gloves should be changed more frequently but does not provide a

[4] California Board of Pharmacy, Staff Recommended Response to Comments – Section 1737 et seq, https://www.pharmacy.ca.gov/meetings/agendas/2025/25_feb_bd_mat_1737_comments.pdf (last visited Feb. 20, 2025).

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		citation to a specific ASHP guidance document.[5] In our comment letter dated December 6, 2024, we conjectured that the Board was referencing ASHP's Guidelines on Handling Hazardous Drugs.[6] If that is the case, we want to be clear that the guideline makes no reference to changing gloves after each different HD preparation or each patient and instead recommends that gloves be changed "every 30 minutes during compounding or immediately when damaged or contaminated," consistent with the USP 800 chapter and the standard of practice.[7] The Board also references a single-center simulation study from 2017.[8] The intent of that study was to assess the spread of a simulated HD residue "placed on the exterior vial surface to downstream surfaces." The study was conducted by covering drug vials with a fluorescent simulated HD residue (Glo Germ powder), compounding a small-volume parenteral solution using the drug in the vial and one of five different Closed System Transfer Devices (CSTD), and then assessing various simulated pharmacy materials and work surfaces and simulated drug administration materials and work surfaces for fluorescence. After each simulated compound was prepared, compounding personnel changed their personal protective equipment, including their gloves, and cleaned and disinfected the pharmacy work surfaces. The study concluded that the use of a closed barrier system—a unique component of one of the five CSTD systems used—might reduce the risk of transferring HD residue from a vial to the drug delivery system. For several reasons, relying on this study to support the notion that outer HD gloves should be changed after each different HD

[5] California Board of Pharmacy, *Modified Initial Statement of Reasons Compounded Drug Products*, https://www.pharmacy.ca.gov/laws_regs/1708_1735_1751_misr.pdf (last visited Feb. 20, 2025).

[6] American Society of Health-System Pharmacists, *ASHP Guidelines on Handling Hazardous Drugs*, https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/handling-hazardous-drugs.ashx (last visited Feb. 20, 2025).

[7] *Id.*

[8] Evan Call et al., Hazardous Drug Contamination of Drug Preparation Devices and Staff: A Contamination Study Simulating the Use of Chemotherapy Drugs in a Clinical Setting, 52 Hosp. Pharm. 551-558 (2017).

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		preparation or each different patient in our opinion exposes deeply flawed reasoning on the Board's part. First, the study did not assess whether changing gloves more frequently than every 30 minutes during HD compounding reduces the spread of HD residue. Moreover, the study only evaluated the spread of HD residue within a compounding cycle for one compounded sterile product; it did not evaluate the spread of HD residue between compounding cycles. In fact, during the study, compounding personnel changed their gloves after each simulated HD preparation was prepared. We invite the Board to explain how they arrived at the conclusion that outer HD gloves cannot safely be used across compounding cycles based on the results of a study that only assessed the spread of HD residue within one compounding cycle. This faulty conclusion should be enough to disqualify this study as "evidence" to support the proposed regulation; however, there is another oversight by the Board that is equally, if not more, disqualifying. This study was conducted on or before 2017, at which time the national standard for sterile compounding practices was the 2008 revision of USP 797. In the list of "suggested standard operating procedures," the 2008 revision of USP 797 ***encouraged***, but did not require decontaminating supplies that are introduced into the aseptic work area.[9] In contrast, Section 8 of the 2023 revision of USP 797 ***requires*** articles to be wiped with a disinfectant or 70% isopropyl alcohol before being introduced into a Secondary Engineering Control ***and*** before being introduced into a Primary Engineering Control.[10] The ASHP Guidelines on Handling Hazardous Drugs recognize wiping surfaces with 70% isopropyl alcohol as an effective method to remove HD surface contamination.[11] California Business and Professions code section 4126.8 already requires pharmacies to meet the requirements of the current USP compounding chapters.[12] Therefore, unlike the

[9] General Chapter: USP. Pharmaceutical Compounding – Sterile Preparations <797>. In: USP–NF. Rockville, MD: USP; 2008.
[10] General Chapter: USP. Pharmaceutical Compounding – Sterile Preparations <797>. In: USP–NF. Rockville, MD: USP; Nov 1, 2023.
[11] ASHP, *supra*.
[12] Cal. Bus. & Prof. Code § 4126.8.

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		referenced study, California law already requires that drug vials are wiped at least twice before they are introduced into a PEC. It is unreasonable to assume that the degree of HD contamination on a vial that was never cleaned, or in the case of the referenced study intentionally 'contaminated', is the same as that of a vial that has been wiped at least twice with 70% isopropyl alcohol or another disinfectant; therefore, the Board's reasoning that this study provides evidence that it is necessary for compounding personnel to change their outer HD gloves after each different HD preparation or each different patient is not justified. All told, nothing has changed from when this proposed regulation was introduced in the spring of 2024; there is no evidence to support the Board's contention that the regulation is "necessary to prevent inadvertent cross contamination."[13] This proposed regulation is a solution in search of a problem that will significantly increase supply costs to pharmacies—which will almost certainly be passed on to consumers—increase medical waste entering the waste stream, increase the likelihood of microbial contamination of compounded sterile products, and incentivize unsafe practices. Given the obvious lack of evidence to support this proposed regulation and the unintended consequences it will likely precipitate, we urge the Board to remove this requirement from the regulations.
1737.15(a)	Deactivating, decontaminating, cleaning, disinfecting, and sporicidal agents shall be used in accordance with manufacturers' specifications, or subsequent ~~manufacturer approved~~ peer reviewed studies, and shall be surface compatible.	We acknowledge the Board's perspective that there should be some mechanism in place to ensure the methodological rigor of studies that are relied upon to justify the use of an alternative agent for deactivating, decontaminating, cleaning, disinfecting, and or and/or killing bacterial and fungal spores in the compounding suite. However, manufacturer "approval" alone does not guarantee methodological rigor any more than publishing the study does. If the Board's primary concern is to ensure methodological rigor in any study that is referenced to justify the use of an alternative agent, then we suggest modifying the regulation text to indicate that the study must be peer reviewed.

[13] Modified Initial Statement of Reasons, *supra*.

Martinez, Lori@DCA

From: Loh Francis <loh1428@yahoo.com>
Sent: Thursday, February 20, 2025 2:04 PM
To: PharmacyRulemaking@DCA
Subject: Third Modified Text Compounding

I am writing to express my frustration with the Board and the proposed compounding regulations. While I understand the need for everyone to have an opportunity to comment, it is frustrating to me that those opposing the regulation are interfering and delaying these regulations.

Based on all the discussions I have listened too and everything I have read, it is clear that what the vast majority of commenters are requesting (access to to specific compounded products from bulk drug substances) is outside the per view of the Board. The Board cannot approve these drugs and cannot authorize them to be compounded. These individuals need to take their fight where it belongs, the FDA.

It is shocking to me that these commenters are threatening Board members and making crazy accusations without any evidence, but then demand the Board to provide evidence.

Protect Californians and pass these regulations now. This has gone on long enough!

Stop accepting the false narrative being put forth by a few and amplified by their followers.

Loh Francis

Marie Cottman, Pharm.D.
Pacific Compounding Pharmacy
1889 W March Ln
Stockton, CA 95207

February 20, 2025

Lori Martinez
Board of Pharmacy
2720 Gateway Oaks Dr. Ste 100
Sacramento Ca 95833

Dear Members of the Board of Pharmacy,

Thank you for the opportunity to participate in the rule-making process and to educate the Members regarding practical and reasonable practices in pharmacy compounding. Further, I respect that the task of making rules for our diverse profession is not easy. This has been exemplified by the challenges you have faced with revisions to the Modified Text of Compounded Drug Products over the last 3 years.

I believe that this rule making has failed to meet the ***intent*** of the process as described in Chapter 3.5- Administrative Regulations and Rulemaking, ARTICLE 1 - General, Sections 11340 and 11340.1. If you are not familiar with it, you can find the full text here (https://law.justia.com/codes/california/code-gov/title-2/division-3/part-1/chapter-3-5/article-1/section-11340/).

In addition to creating a more transparent process that included public participation, Section 11340 enumerates ***why*** our rule making process exists. In the 1994, the California Legislature recognized the following (paraphrased) facts:

a) There had been an unprecedented growth of administrative regulations,
b) Law language created unclear and unnecessarily complex regulations,
c) Substantial time and public funds were spent to adopt regulations that may not be necessary,
d) The imposition of prescriptive standards on entities through regulations that place an unnecessary burden and discourage innovation, research, and development and
e) The complexity and lack of clarity of regulations put small businesses at a distinct disadvantage

THUS the Legislature established the Office of Administrative Law (OAL) to

1. Review adopted regulations
2. Reduce the number of administrative regulations and
3. Improve the quality of those regulations.

With the **INTENT** that

- Agencies shall actively seek to reduce the regulatory burden on private entities by substituting performance standards for prescriptive standards wherever performance standards can be reasonably expected to be as effective and less burdensome, and that this substitution shall be considered during the course of the agency rulemaking process.

Have you ever read these sections before? Thankfully, this is why I have a voice in making rules for my beloved profession!

I believe you, too, can recognize that this particular rule making process is not aligned with the intent of these sections. Despite good intentions, here are several ways that the process has fallen short of the INTENT of the rule making process (lettered relative to the sections above):

a) This rule making process is **creating** more rules than it is repealing.
b) As evidenced by the volume of comments that you have received and the number of revisions you have had to publish, **these rules remain unclear and unnecessarily complex.**

c) This rule making process started 3 years ago on January 28, 2022. The number of hours spent on this rule making by Board Members, Board Staff, Attorneys, and all the stakeholders is clearly **substantial...** all in an effort to adopt regulations that may not be necessary (as USP is an adequate performance standard).
NOTE: Throughout the rule making process, several commenters have asked for the Board to provide evidence or data to support that these proposed rules will ***improve*** patient safety and to my knowledge, no valid data or evidence has been provided. The comment responses continue to be "Board Staff have reviewed the comment and do not recommend any changes..." or similar to this. If facts or data are not presented to justify the staff's rationale, then it must just be an opinion. What credentials do the staff have to rank them as experts in the topic of pharmaceutical compounding? Certainly, they must be at least equally qualified as the members of the USP committee, no?

d) I can guarantee that these rules and regulations **will discourage innovation, research, and development** of custom compounded medication solutions for patients in need. Additionally, these regulations **will increase costs** which will further impede access to necessary therapies for the California public.

e) Most of your licensed compounders are small businesses, like mine. I have 10 employees. We provide unique services to 1,500 patients per month. Without a doubt, my business, and much more importantly, my patients, will be adversely affected by these proposed rules.

Summatively, over the last three years, the Board Staff have neglected to answer the most important question: How do these "in addition to USP Chapters" requirements ACTUALLY improve patient safety beyond the full adoption of the USP Compounding Chapters? There has been no evidence presented in the comment replies or at the hearings that these proposed prescriptive standards will, in fact, improve patient safety. Rather, I would argue that the performance standards provided throughout the USP Chapters are sufficient guidance for your licensees to result in safe compounds. Additionally, the regulatory burden of these proposed prescriptive requirements can be reasonably expected to be MORE burdensome and MORE expensive, but NOT result in safer compounds. As evidence of this, I remind you that the Board Staff stated in the last Comment Responses "Board staff notes that a variety of nonpharmacy personnel have authority to compound including for example physicians and veterinarians." And compound they will, if these regulations go through! Their regulatory bodies will allow them to compound in compliance with the standards of USP which will be more cost effective for patients, who will elect NOT to have a pharmacist prepare their compound.

I implore you to **REJECT** the Recommended Third Modified Text of Compounded Drug Products dated January 30, 2025. After three years of discussions and revisions, this text does not meet your mandate of Protecting the Public any better than if your licensees comply with the USP Chapters as written by the expert committees over a 12 year period from 2010-2022.

As an alternative, I **RECOMMEND** that you move forward with a repeal of sections 1735-1735.8 of Article 4.5 and repeal sections 1751-1751.12 of Article 7 without any additional revision or adoption of rules. All of the USP compounding chapters are codified in BPC Section 4126.8 and can stand on their own until such time as rulemaking for requirements *proven* to improve patient safety can commence.

Respectfully submitted,

Marie Cottman, Pharm.D.
Owner/PIC

Subdivision	Board Proposed Language	Recommendation / Comment
1735.1(e)(2)	(2) Is made with any component not suitable for use in a CNSP for the intended veterinary population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA). When a veterinarian, acting within a valid veterinarian-client-patient relationship (VCPR), determines there is no medically appropriate human or animal drug that is FDA-approved, conditionally approved, or indexed to treat the animal, a pharmacy may use a bulk drug substance to compound an animal drug. 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.	**Recommendation:** Amend to remove the last sentence: ~~This compound shall be in compliance with the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022.~~ **Comments:** "Shall be in compliance with a [document]" This statement is far too non-specific as the GFI document contains Intro, Background, Paperwork Reduction Act and Appendices that link to websites. Specifically, what part of the 21 page GUIDANCE document SHALL we comply with? And what happens to 1735.1(e)(2) when the document changes or goes obsolete (yes the OMB has an expiration date on the document)? If you want additional required items that compounders should comply with for veterinary preparations, please don't make us hunt and peck for the language you are looking for, spell it out. Labeling? Documentation? Bulk Drugs for office use? Reporting ADEs to the FDA? What are you looking for???? It describes "The circumstances under which, at this time, FDA does not generally intend to take enforcement action against drugs compounded from bulk drugs substances for violations of the FD&C Act's requirements for approval, adequate directions for use, and CGMPs." The FDA states that it "generally does not intend to take enforcement action against" NINE (9) times in the document! GFI 256 is written as GUIDANCE, not as regulation nor law. It describes "The circumstances under which, at this time, FDA does not generally intend to take enforcement action against drugs compounded from bulk drugs substances for violations of the FD&C Act's requirements for approval, adequate directions for use, and CGMPs." Several items that are vague or open to interpretation. As well as statements that outright conflict with each other. Do compounders comply with the statement on pg 5 that: "drugs compounded from bulk drug substances violate the FD&C Act because they are not approved or indexed, are not made according to CGMP, and cannot satisfy the FD&C Act's adequate directions for use provision (which requires, among other things, that a prescription drug have FDA-approved labeling). " Or the statement also on pg 5: "[the] FDA recognizes that there are circumstances in which no FDA-approved or indexed drug (including the extralabel use of an FDA-approved animal or human

		drug) can be used to treat an animal with a particular condition. In those limited circumstances, an animal drug compounded from bulk drug substances may be a medically appropriate treatment. " Do we, as licensees assume that we should replace BOP wherever we see FDA in the document such as "This guidance describes: • The types of drugs compounded from bulk drug substances that FDA[BOP] has determined present the greatest risk to human and animal health and intends to make priorities for enforcement action; and • The circumstances under which, at this time, FDA [BOP[does not generally intend to take enforcement action against drugs compounded from bulk drugs substances..."
1735.1 (f)	(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.	**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. 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.
1735.1 (g)	(g) In addition to the provisions in section 1707.2, consultation includes proper use, storage, handling, and disposal of the CNSP and related supplies furnished.	**Recommendation:** Amend redundant language. (g) In addition to the provisions in section 1707.2, 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.

1735.10(b)(2)	(b) A CNSP's BUD shall not exceed any of the following: (2) The compatibility and degradation of the container–closure system with the finished preparation (e.g., possible leaching, interactions, and storage conditions),	**Recommendation:** Remove this section. If you won't remove it, then please consider a rewrite: *(b) A CNSP's BUD shall be conservatively assigned when data is not readily available to validate chemical and physical stability or compatibility and degradation with the container-closure system.* **Comment:** USP already addresses what to consider when determining BUDs. I ***repeat*** my previous concerns! It is not clear who has the burden of proof that the CNSP is reactive or non-reactive with the container- closure system. This data is rarely readily available (compounder or Board)! Amber bottles, ointment jars, and oral syringe container closures are standard in the field of compounding, but where are the studies for the hundreds of APIs that we use to solve unique patient issues? And again, the testing to provide proof of compatibility is many $1,000s! Under this proposed rule, when a prescriber identifies a novel drug delivery device for a unique patient experience, **compounders will be unable to package the compound they don't have proof** (even if there is good similar data available). If the pharmacist were to apply a conservative 14 day refrigerated BUD, without specific data, they *could* be in violation of this rule and subject to action against their license. *This will limit access to compounds for patients with unique needs!*
1735.12(b)	(b) The Board shall be notified in writing within 96 hours of the facility's receipt of a complaint of a potential quality problem involving a CNSP.	**Recommendation:** Amend to clarify. The Board shall be notified in writing within 96 hours of the facility's receipt of a complaint ~~of a~~ determined to be a potential quality problem involving a CNSP. **Comments:** Clarifying this wording will prevent unnecessary communications with the Board about complaints NOT related to a compounding ***quality*** issue.
1735.13	1735.13. CNSP Packaging and Transporting. ***In addition*** to the standards set forth in USP Chapter 795, the facility shall ensure appropriate processes for storage, shipping containers and temperature sensitive CNSPs as provided for in the facility's SOPs. (emphasis added)	**Recommendation:** Remove **Comments:** This statement does not provide anything in addition to USP 795 quoted here: *USP 795 13.1 Packaging of CNSPs states: "The facility's SOPs must describe packaging of CNSPs. Personnel should select and use packaging materials that will maintain the physical and chemical integrity and stability of the CNSPs. Packaging materials must protect CNSPs from damage, leakage, contamination, and degradation, while simultaneously protecting personnel from exposure. And 13.2 Transporting of CNSPs* *"If transporting CNSPs, the facility must have written SOPs to describe the mode of transportation, any special handling instructions, and* *whether temperature monitoring devices are needed."*

1736.1(e)(2)	(2) Is made with any component not suitable for use in a CSP for the intended veterinary population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA). When a veterinarian, acting within a valid veterinarian-client-patient relationship (VCPR), determines there is no medically appropriate human or animal drug that is FDA-approved, conditionally approved, or indexed to treat the animal, a pharmacy may use a bulk drug substance to compound an animal drug. 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.	**Recommendation:** Amend to remove the last sentence: ~~This compound shall be in compliance with the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022.~~ **Comments:** "Shall be in compliance with a [document]" This statement is far too non-specific as the GFI document contains Intro, Background, Paperwork Reduction Act and Appendices that link to websites. Specifically, what part of the 21 page GUIDANCE document SHALL we comply with? And what happens to 1735.1(e)(2) when the document changes or goes obsolete (yes the OMB has an expiration date on the document)? If you want additional required items that compounders should comply with for veterinary preparations, please don't make us hunt and peck for the language you are looking for, spell it out. Labeling? Documentation? Bulk Drugs for office use? Reporting ADEs to the FDA? What 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). " 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..."
1736.1 (f)	(f) Prior to allowing any CSP to be compounded within a pharmacy, the pharmacist-in-charge shall complete a self-assessment consistent with the requirements established in section 1715.	**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. 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.
1736.1 (g)	(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.	**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.

1736.8	In addition to the requirements in USP Chapter 797, the following requirement applies to sterile compounding. Introducing items into the SEC and PEC shall comply with the SOPs as required in section 1736.17.	**Recommendation:** Remove this section. **Comment:**I reiterate my previous comments that this is addressed adequately in proposed 1736.17. The rationale provided by Staff after the last revision that "this section serves as a reminder," is a substandard rule making 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.

1736.9(d)	(d) All APIs used to compound a CSP shall be manufactured by an FDA-registered facility, be accompanied by a Certificate of Analysis (COA), and be suitable for use in sterile pharmaceuticals. A COA that includes the compendial name, the grade of the material, and the applicable compendial designations on the COA, must be received and evaluated prior to use, unless components are commercially available drug products. When the COA is received from a supplier, it must provide the name and address of the manufacturer. An API provided with a COA without this data shall not be used in a CSP.	**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***
		• ***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 standars***
		  ○ ***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 sourc and require that wholesalers must comply with.

1737.7(a)	(c) Outer gloves used for HD compounding shall be changed between each different HD preparation, unless preparing multiple HD preparations of the same drug or preparing multiple HD preparations for a single patient.	**Recommend to remove.** **Comment:** Board Staff appears to be finding evidence to fit it's narrative. The evidence that this proposed regulation is "addressing the potential for cross-contamination" references an article Hazardous Drugs Contamination of Drug Preparation Devices and Staff: A Contamination Study Simulating the use of Chemotherapy Drugs in a Clinical Setting. **This is a seriously flawed study** to demonstrate cross contamination in an ACTUAL HD Cleanroom!!! Did Staff read the methods? In this demonstration, the methods state that "Fifteen drug vials, containing only sterile saline, were placed in a separate room and coated with the Glo Germ powder at 90% coverage." OF COURSE YOU WILL HAVE CROSS CONTAMINATION!! The results of this intentional 90% contamination of a powder on the ***outside*** of the vials is not a scenario that is transferable to real-world sterile HD situations! This study was published in 2017, several years prior to the widespread use of 800 rooms and HD protocols. To advocate for this expensive and time consuming regulation, you will need better evidence that typical chemo/HD vials are significantly externally contaminated often enough directly from the manufacturers to warrant the proposed HD cleanroom gloving behavior change. Additionally, USP 800 FAQ 53. **When do HD PPE components need to be removed?** The outer pair of sterile HD gloves (tested to ASTM D6978) are removed inside the C-PEC prior to leaving the C-PEC. They must be placed in a trace HD container (such as a bag or small rigid yellow bin) inside the hood. USP does NOT recommend that Gloves be changed between each preparation. As I presented to the board previously, this proposed rule remains an expensive and unnecessary rule. Sterile gloves cost $1.50 to $3.85 / pair. In addition to the expense, this change in process for all sterile HD compounders might result in a shortage of gloves because the use will not double, but it might increase by 10 or 20 fold!

NATIONAL CONSUMERS LEAGUE
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Ms. Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Drive
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Sacramento, CA 95834
E-Mail Address: PharmacyRulemaking@dca.ca.gov

February19, 2025

RE: Modifications to Title 16 CCR Sections 1735 et seq, 1736 et seq, 1737 et seq, and 1738 et seq Related to Compounded Drug Preparations, Hazardous Drugs and Radiopharmaceuticals.

To Whom It May Concern:

The National Consumers League (NCL) is a private, nonprofit consumer education and advocacy organization founded in 1899 to represent the voice of consumers on matters affecting social justice, consumer protection and the wellbeing of the American public.

Especially as our work relates to nutrition and health, NCL is deeply concerned about the growing epidemic of obesity, which now affects 41.9 percent of US adults [1] – more than 100 million people – as well as 27.7 percent of Californians. [2] Besides being a serious chronic disease that negatively impacts almost every aspect of health and well-being, obesity worsens the outcomes of over 230 obesity-related chronic diseases,[3] is linked to approximately 400,000 premature deaths each year[4] and costs the U.S. economy an estimated $1.72 trillion annually.[5]

While these facts should disturb all Americans, the reality is that obesity is still not viewed as a serious disease and health plans routinely exclude coverage for FDA-approved anti-obesity medications. Thus, too many Americans opt for unauthorized or counterfeit versions of weight loss drugs, and especially injectable glucagon-like peptide-1 receptor agonists (GLP-1s) used to treat diabetes and obesity.

It is because of issues like this that NCL worked with the National Council on Aging and leading obesity experts to issue the first ***Obesity Bill of Rights*** for the nation so people with obesity will be screened, diagnosed, counseled, and treated according to medical guidelines. First among these rights is having accurate, clear, trusted and accessible information about obesity, which must include being warned about fake GPL-1s and the potential health consequences.

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[1] Stierman B, Afful J, Carroll MD, et al. National Health and Nutrition Examination Survey 2017–March 2020 prepandemic data files development of files and prevalence estimates for selected health outcomes. Natl Health Stat Report. 2021;158

[2] United Health Foundation. America's Health Rankings. Accessible at: https://www.americashealthrankings.org/explore/measures/Obesity/CA

[3] Obesity Care Advocacy Network. Fact Sheet: Obesity Care Beyond Weight Loss

[4] Hurt Ryan T et al. Obesity epidemic: overview, pathophysiology, and the intensive care unit conundrum. J Parenter Enteral Nutr. 2011 Sep;35(5 Suppl):4S-13^

[5] Milken Institute (October 2018), "America's Obesity Crisis: The Health and Economic Costs of Excess Weight."

The bill of rights also establishes the right to person-centered care, which necessitates that GLP-1s are produced safely and responsibly under the supervision of a qualified health provider and supplied by a licensed manufacturer or pharmacist.

In furtherance of these rights, on February 5, NCL issued a national alert calling on consumers and health professionals to heed the warnings from the Food and Drug Administration[6] that compounded versions of GLP-1 drugs now widely promoted on television and online are not FDA approved and may cause serious health problems. As the alert makes clear, an unregulated marketplace now exists where online telehealth companies and pharmacies are marketing untested compounded GLP-1 drugs or actual counterfeits that, according to the FDA, may contain incorrect dosages, the wrong ingredients, too much, too little or none of the active ingredients, and possibly bacteria. Even more worrying, a 2024 report from the National Association of Boards of Pharmacy[7] warns that illegal online pharmacies are selling substandard or falsified GLP-1 agonists without holding the required pharmacy licensure and without requiring a valid prescription.

Due to the serious health consequences associated with unapproved compounded weight loss drugs, a number of medical organizations and state Attorneys General have joined with NCL in issuing warnings that urge consumers to obtain prescriptions for GLP-1 medications from a trusted health provider and to fill the prescription an appropriately licensed pharmacy. At the same time, several state boards of pharmacy have issued public alerts and/or released policy statements directing compounders to comply with federal regulations. This is to ensure that compounding does not become a loophole for marketing knockoffs of available FDA-approved GLP-1 drugs.

Recently, we learned that the California State Board of Pharmacy is considering modifications to its rules related to compounded drug preparations that we believe are inconsistent with federal law and may compromise patient safety. Thus, we encourage the Board to consider the existing fraud and patient harm from the lax controls over compounded GLP-1 drugs when finalizing its rulemaking.

While the amended rules govern compounded drugs generally, the situation regarding untested, widely promoted and widely available compounded and counterfeit GLP-1s should be guidepost for determining the circumstances under which drugs should be compounded during a shortage and the requirements for reporting adverse reactions. Accordingly, NCL urges the Board to maintain federal requirements that spell out when compounding drug products is allowed as essentially copies of FDA-approved, commercially available drugs. Additionally, we believe that mandating compounding facilities to report adverse events associated with sterile and nonsterile compounded products is essential to identify potential quality issues and safety problems.

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[6] Food and Drug Administration. December 18, 2024. "FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss." Accessible at: https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss

[7] National Association of Boards of Pharmacy. "Injectable Weight Loss Drugs: How Illegal Online Drug Sellers Are Taking Advantage of Patients." April 24, 2024. Accessible at: https://nabp.pharmacy/wp-content/uploads/2024/04/RogueRx-Activity-Report-Injectable-Weight-Loss-Drugs-2024.pdf

Thank you in advance for your consideration of these comments.

Sincerely,

Nancy Glick

Nancy Glick, Director, Food & Nutrition Policy
National Consumers League
nancyG@nclnet.org
202-320-5579

February 21, 2025

Department of Consumer Affairs, Board of Pharmacy
First Floor Hearing Room
2720 Gateway Oaks Dr., Ste 100
Sacramento, CA 95833

Re: Novo Nordisk Inc. Comments to California Board of Pharmacy Notice of Proposed Regulatory Action Concerning Compounded Drug Products, Third Modified Text

To Whom It May Concern:

Novo Nordisk Inc. ("NNI") appreciates this opportunity to submit comments in response to the California Board of Pharmacy (the "Board") Notice of Proposed Regulatory Action Concerning Compounded Drug Products, Third Modified Text ("Proposed Rule" or "Third Modified Text").[1]

Novo Nordisk is a healthcare company with a 100-year history of innovation in developing medicines to treat serious chronic diseases, like diabetes and obesity. NNI is the only company in the United States with FDA-approved medicines containing semaglutide. Semaglutide is the foundational molecule that serves as the primary ingredient for Novo Nordisk's well-known, prescription only medicines: Rybelsus® (semaglutide) tablets to improve glycemic control in adults with type 2 diabetes; Ozempic® (semaglutide) injection to improve glycemic control in adults with type 2 diabetes, to reduce the risk of major adverse cardiovascular events ("MACE") in adults with type 2 diabetes and established cardiovascular disease, and to reduce the risk of sustained eGFR decline, end-stage kidney disease and cardiovascular death in adults with type 2 diabetes and chronic kidney disease; and Wegovy® (semaglutide) injection to reduce the risk of MACE in adults with established cardiovascular disease and either obesity or overweight or for chronic weight management in adult and pediatric patients with obesity or adults with overweight.

We appreciate the Board's continued effort to propose regulations on compounding that center around the wellbeing of patients. While we appreciate the Board Staff's providing the Staff Responses to our comments on the Second Modified Text, we think the issues raised merit further consideration by the Board. Further, the Staff Responses do not address some key points raised in NNI's prior comments on the Second Modified Text. We offer additional comments and recommendations below to help align the Board's Proposed Rule with federal standards on the distribution and use of safe and effective drugs. These recommendations also

[1] Notice of Proposed Regulatory Action Concerning: Compounded Drug Products, https://www.pharmacy.ca.gov/laws_regs/1735_npa_24.pdf; Third Modified Text, https://www.pharmacy.ca.gov/laws_regs/1708_tmrt.pdf.

will further enhance the health and welfare of patients who are given compounded drug products.

We provide our comments on the Board's Proposed Rule, using the Board's requested format, below.

Section, Subdivision	Proposed Language in Third Modified Text	Comment / Recommended Language Revision
1735.1(e)(1)	(e) In addition to prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, unless: (A) the 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 or **within 60 days of the end of the ~~shortage 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**	**Comment:** We reiterate our request that the Board update Section 1735.1(e)(1) to state only the prohibition on compounding of "essentially a copy of one or more commercially available drug products," as defined at Section 17735(d), and to remove the exceptions to the copies restriction at (e)(1)(A) in the Third Modified Text related to shortage lists and inability of a health care facility to obtain a drug. In doing so, we ask that the Board reconsider the positions stated in the Staff Responses to NNI's comments to the Second Modified Text. As explained in NNI's prior comments, the exemptions in the proposed regulations from the copies prohibition are overly permissive and inconsistent with federal law and policy. The regulations would allow drugs to be compounded under circumstances that are inconsistent with FDA's current interpretation of Section 503A of the FDCA stated in the agency's 503A Copies Guidance.[2] There, FDA states that the agency does not consider a drug to be "commercially available" within the meaning of the federal copies restriction if it is present on FDA's drug shortage list, and when the drug product has been discontinued and is no longer marketed.[3] The exemption that would permit compounding of copies when a drug product appears on the ASHP drug shortage list is clearly inconsistent with FDA's stated position – FDA has nowhere recognized that listing on the ASHP Drug Shortage list can permit compounding of copies; the agency has only stated as such with regard to FDA's drug shortage list. The proposed regulations are untenable in this respect, evidenced by the fact that the Staff Response to NNI's prior comments does not defend the reference to the ASHP list. Additionally, the proposed regulations would allow for compounding of copies when a health care facility "cannot obtain" a drug from the manufacturer or wholesaler. The Staff

[2] FDA, *Guidance for Industry: Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act* 5 (2018), https://www.fda.gov/files/drugs/published/Compounded-Drug-Products-That-Are-Essentially-Copies-of-a-Commercially-Available-Drug-Product-Under-Section-503A-of-the-Federal-Food--Drug--and-Cosmetic-Act-Guidance-for-Industry.pdf.

[3] *Id.*

Section, Subdivision	Proposed Language in Third Modified Text	Comment / Recommended Language Revision
	(B) The pharmacist ~~determines~~ **verifies** and documents that the compounding produces a clinically significant difference for the medical need of an identified individual patient~~, as determined by:~~ ~~(i) the prescribing practitioner,~~ ~~(ii) the compounding pharmacist, and~~ ~~(iii) the dispensing pharmacist(s). (C) Documentation describing the conditions in (1)(A) & (1)(B) is maintained in a readily retrievable format.~~ (C) Documentation describing the conditions in (1)(A) ~~&~~ **and** (1)(B) is maintained in a readily retrievable format.	Responses point to a footnote in FDA's 503A Copies Guidance that states that the agency is considering the applicability of its policies described in the guidance to hospitals and health systems. Contrary to the staff's statement, FDA has promulgated draft guidance regarding application of the restriction on compounding copies to hospital and health system pharmacies.[4] Therein, FDA states that "[i]n general, FDA intends to apply the policies described in the 503A copies guidance when it regulates compounding by hospital and health system pharmacies that are not registered as outsourcing facilities."[5] While the agency does provide some flexibilities for such entities with regard to the prescriber determination requirement, FDA does not state any policy that would exempt these compounders from the copies restriction altogether based on the inability of the compounder to obtain a drug product from the manufacturer or wholesaler. Rather, FDA's policies regarding shortage stated in the 503A Copies Guidance would apply equally to hospitals and health systems. To best protect patient safety and the public health, and to avoid undermining a key check on compounding of unapproved drug products, we request removing, or at the very least narrowing, the broad permission for health care facilities to compound copies. **Recommended language revision:** "(e) In addition to prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, as defined at Section 1735(d) of this article. Documentation by the pharmacist that the compounded drug product produces a clinically significant difference for the medical need of an identified individual patient, as provided for at Section 1735(d) of this Article, must be maintained in a readily retrievable format."
1736.1(e)(1)	(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP shall be prepared that:	**Comment:** We recommend that the Board amend Section 1736.1(e)(1) to state only the prohibition on compounding of "essentially a copy of one or more commercially available drug products," as defined at Section 17736(e), for the same reasons as described above in our comments on Section 1735.1(e)(1) of the nonsterile compounding regulations. In doing so, we ask

[4] FDA, *Draft Guidance for Industry: Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act* (2021), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/hospital-and-health-system-compounding-under-section-503a-federal-food-drug-and-cosmetic-act.

[5] *Id.* at 7.

Section, Subdivision	Proposed Language in Third Modified Text	Comment / Recommended Language Revision
	(1) Is essentially a copy of one or more commercially available drug products, unless: (A) the 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 or 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 compounding produces a clinically significant difference for the medical need of an identified individual patient~~, as determined by:~~ ~~(i) the prescribing practitioner,~~ ~~(ii) the compounding pharmacist, and~~ ~~(iii) the dispensing pharmacist(s). (C) Documentation describing the conditions in (1)(A) & (1)(B) is maintained in a readily retrievable format.~~ (C) Documentation describing the conditions in (1)(A) & (1)(B) is maintained	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, and to avoid undermining a key check on 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."

Section, Subdivision	Proposed Language in Third Modified Text	Comment / Recommended Language Revision
	in a readily retrievable format.	
1736.9(d)	In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding. (d) All APIs ~~and excipient components~~ used to compound a CSP shall be manufactured by an FDA-registered facility, be accompanied by a Certificate of Analysis (COA)~~,~~ and be suitable for use in sterile pharmaceuticals. A COA that includes the compendial name, the grade of the material, and the applicable compendial designations on the COA, must be received and evaluated prior to use, unless components are commercially available drug products. 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.	**Comment:** 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 have caused the adverse event. The PEG 40 castor oil used was ungraded and not suitable for human consumption or therapeutic use. FDA thus warned against the "risks associated with compounded drugs, particularly those that use non-pharmaceutical grade components and ingredients lacking a USP monograph."[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

[6] FDA, FDA investigates two serious adverse events associated with ImprimisRx's compounded curcumin emulsion product for injection (content current as of June 21, 2018), https://www.fda.gov/drugs/human-drug-compounding/fda-investigates-two-serious-adverse-events-associated-imprimisrxs-compounded-curcumin-emulsion.

[7] *Id.*

Section, Subdivision	Proposed Language in Third Modified Text	Comment / Recommended Language Revision
		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 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 impurities[9] 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

[8] Morten Hach et al., *Impact of Manufacturing Process and Compounding on Properties and Quality of Follow-On GLP-1 Polypeptide Drugs* at 8, PHARM RES. (2024), https://pubmed.ncbi.nlm.nih.gov/39379664/; *see also* Novo Nordisk, Dear HCP letter (Feb. 2024), https://www.novomedlink.com/content/dam/novomedlink/semaglutide/Compounding-Letter.pdf.

[9] *See* Novo Nordisk, Novo Nordisk escalates legal actions to safeguard patients from potentially harmful compounded "semaglutide" drugs (May 2024), https://www.novomedlink.com/content/dam/novomedlink/semaglutide/May-30-2024-Company-Statement.pdf.

[10] Morten Hach et al., *Impact of Manufacturing Process and Compounding on Properties and Quality of Follow-On GLP-1 Polypeptide Drugs* at 8, PHARM RES. (2024), https://pubmed.ncbi.nlm.nih.gov/39379664/.

Section, Subdivision	Proposed Language in Third Modified Text	Comment / Recommended Language Revision
		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 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."
1736.9(e) and 1736	(e)(1) Except as provided in (2), ~~When~~ when a bulk drug substance or API is used to compound a CSP, it shall comply with a USP drug monograph, be the active substance of an FDA approved drug, or be listed in 21 CFR **section** 216, or unless authorized by a public health official in an emergency use situation for a patient-specific compounded sterile preparation.	**Comment:** We appreciate the Board's goal of aligning the 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 the conditions under which sterile compounding can occur. By adopting this recommendation, the Board will align its Proposed Rule with Federal Food, Drug, and Cosmetic Act section 503A(b)(1)(A). We also 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.

Section, Subdivision	Proposed Language in Third Modified Text	Comment / Recommended Language Revision
		Recommended language revision: 1736.9: "(e)(1) Except as provided in (2) or (4), when API is used to compound a CSP, it shall – (i) comply with a USP monograph; (ii) if such a monograph does not exist, be an API that is a component of a drug approved by the FDA; or (iii) if such a monograph does not exist and the API is not a component of a drug approved by the FDA, be listed in 21 C.F.R. § 216.23." *[NEW]* "(4) A drug product may be compounded if authorized by a public health official in an emergency use situation for a patient-specific compounded sterile preparation. (5) API used to compound a CSP that claims to be a component of an FDA-approved drug must be manufactured by the process specified in the labeling of the FDA-approved drug." 1736: *[NEW]* "(i) 'Component of a drug approved by the FDA' means an API that is the same as the API used in the manufacture of the approved drug."

Thank you for the opportunity to provide comments on this Proposed Rule. We would be pleased to provide further input or clarification of our comments if needed.

Sincerely,

Robert B Clark

Robert B. Clark
Vice President, Regulatory Affairs
Novo Nordisk Inc.

"Our Mission, Your Voice: Empowering Change Together"

February 20, 2025

California Department of Consumer Affairs
Board of Pharmacy
First Floor Hearing Room 2720
Gateway Oaks Dr., Ste 100
Sacramento, CA 95833

RE: Third Modified Text - Division 17 of Title 16 of the California Code of Regulations - Board of Pharmacy

Dear Members of the Board of Pharmacy,

The Obesity Action Coalition (OAC) is the leading national non-profit organization dedicated to giving a voice to individuals affected by the disease of obesity. The OAC proudly serves 6,244 members living in California and is backed by more than 85,000 members across the United States. Obesity is a complex chronic disease driven by strong biology, not by personal choice. Throughout the past decades, the prevalence of obesity has skyrocketed across our country and in California – with 28 percent of adults and 17 percent of children (ages 6-17) in the state currently affected by obesity.[1]

The OAC appreciates the opportunity to comment on Division 17 of Title 16 of the California Code of Regulations - Board of Pharmacy, specifically sections 1735.1(e)(1)(A) Introduction and Scope, 1735.11. Standard Operating Procedures (SOPs), and 1735.12 Quality Assurance and Quality Control - to ensure limited availability of quality compounded GLP-1 products and strict standards for adverse event reporting.

Section 1735.1(e)(1)(A) - Introduction and Scope

We recommend that the Board update Section 1735.1(e)(1)(A) to align with FDA's interpretation of Section 503A that would only allow drugs to be compounded under certain circumstances. The proposed exceptions to the copies restriction at (e)(1)(A) in the Third Modified Text – are overly discretionary for healthcare facilities

[1] Trust for America's Health, State of Obesity 2024: Better Policies for a Healthier America. https://www.tfah.org/report-details/state-of-obesity-2024/

related to shortage lists and their inability to obtain a drug. The proposed Third Modified Text, would further allow drugs to be compounded under circumstances when a drug product appears on the American Society of Health-System Pharmacists (ASHP) list. These broad exceptions are inconsistent with federal law and current policy and could perpetuate the manufacturing of illicit and unapproved compounded drug products when FDA-approved drugs are available to patients.

Sections 1735.11. Standard Operating Procedures (SOPs) & 1735.12 Quality Assurance and Quality Control

Compounded drugs lack the same level of safety, efficacy, and quality assurances of FDA-approved drugs, and compound facilities and pharmacies lack adequate systems for tracking and tracing and reporting adverse events associated with their drugs. OAC strongly recommends reinserting all references to "adverse drug experiences" to ensure that compounding facilities are required to notify the Board of adverse events involving compounded products. As you know, compounding pharmacies are not required to do surveillance, evaluation, or reporting of adverse events to FDA. It is unacceptable to put the onus on the patient who purchases a compounded drug from a retail pharmacy to report adverse events to the outsourcing compounding facility. How could they, given they have no knowledge or direct connection? The risk of missed adverse events is amplified when compounding facilities partner with telehealth companies and other online vendors that do not conduct adverse event reporting. Requiring adverse event reporting and limiting distribution to products strengthens safety, control of the process, and communication to patients.

General Comments

Among the patient community, we fear the growth of compounded GLP-1 products will endanger patients and create a sub-standard of care. Compounded GLP-1 drugs were never intended to be widely marketed and distributed to treat chronic disease. It is difficult to name another disease state or therapeutic area with widespread compounding and outsourcing combined with predatory marketing strategies for treatments. For example, we don't see these practices with cancer patients, where someone can purchase chemotherapy at the local medi-spa or by filling out a form with an online telehealth vendor. It's also not acceptable for the treatment of obesity.

People living with obesity have a right to FDA-approved medications and should not be subject to sub-standard healthcare. Policy reforms to address ongoing supply shortages and affordability barriers is critical to improve equitable access to safe, effective obesity care for all people living with obesity. **The OAC appreciates the opportunity to comment on Division 17 of Title 16 of the California Code of Regulations - Board of**

OAC Obesity Action Coalition | 20 YEARS SINCE 2005

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Pharmacy to ensure limited availability of quality compounded GLP-1 products and strict standards for adverse event reporting.

As a voice for people living with obesity, OAC looks forward to working with the state of California to ensure Californians have access to safe and FDA-approved treatments for this complex and chronic disease. We would be happy to meet and share further information and perspectives of people living with obesity. Should you have questions or need additional information, please reach out to our Policy Advisor, Chris Gallagher at chris@potomaccurrents.com. Thank you.

Sincerely,

Joe Nadglowski
President & CEO
Obesity Action Coalition

SAFE ▪ EFFECTIVE ▪ SOLUTIONS

OFA

OUTSOURCING FACILITIES ASSOCIATION

February 21, 2025

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
PharmacyRulemaking@dca.ca.gov
(916) 574-8618

Re: Notice of Proposed Action: Compounded Drug Products Third Modified Text

The Outsourcing Facilities Association ("OFA") is the trade association representing FDA-registered outsourcing facilities operating pursuant to Section 503B of the Federal Food, Drug, and Cosmetic Act ("FDCA"). OFA's members provide compounding and repackaging services to patients, healthcare providers, and healthcare facilities, and strive to ensure the specific needs of both providers and patients are met with safe and effective compounded and/or repackaged medications under the current Good Manufacturing Practices standards and guidance of the Food and Drug Administration and in compliance with all applicable laws and regulations.

OFA submits this comment concerning the second modified text of certain proposed amendments to Title 16 of the California Code of Regulations, as follows:

Outsourcing Facilities Association; c/o: Victoria Weatherford		
Section, Subdivision	Proposed Language	Recommendation / Comment
Proposed § 1735.1(e)	(e) In addition to prohibitions and requirements for compounding established	The proposed amendment should be revised for additional clarity, for the reasons stated below

	in federal law, no CNSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, unless: ..., or (B) The pharmacist verifies and documents that the compounding produces a clinically significant difference for the medical need of an identified individual patient.	

On December 9, 2024, OFA submitted a comment (the "December 2024 Comment") addressing prior proposed text of § 1735.1. The December 2024 comment explained, *inter alia*, that a requirement that a finding of clinically significant difference be made by "the prescribing practitioner," "the compounding pharmacist," and "the dispensing pharmacist(s)" was arbitrary, capricious and contrary to law. The proposal demanded that pharmacists engage in the practice of medicine in contravention of California law, imposed obstacles to federal policies under the FDCA in contravention of federal law, and operated in erratic ways for no rational policy objective. The December 2024 Comment is incorporated here by reference.

The Second Modified Text, published on or about January 10, 2025, appears in relevant part intended to address OFA's objections or at least those along similar lines. The Second Modified Text of Proposed § 1735.1 avoids demanding that pharmacists practice medicine by requiring only that a "pharmacist verifies and documents" a clinically significant difference, rather than make the *determination* of clinically significant difference, which the prescribing practitioner must do under federal law. With the text so understood, the objections stated in the December 2024 Comment would be resolved.

However, the Second Modified Text of Proposed § 1735.1(e) may fall short of achieving these objectives because it is arguably ambiguous concerning (1) what is to be verified and documented and (2) what verification and documentation is required.

First, the shift from a *determination* standard to a *verification and documentation* standard indicates that the pharmacist under the Second Modified Text need only verify and document that a prescribing practitioner has made a finding of clinically significant difference. But there is an arguable ambiguity: the draft text's reference

to verifying and documenting directly "that the compounding produces a clinically significant difference" could be misunderstood to require that pharmacists find an actual clinically significant difference in possible conflict with doctors' findings, which would raise all the flaws identified in the December 2024 Comment and be unlawful on the grounds stated there. The text should be revised to make clearer that the pharmacist must verify and document that *the prescriber* has made such a determination.

Second, the Second Modified Text is also arguably ambiguous as to what type of verification and documentation is sufficient. As drafted, the Modified Text of Proposed § 1735.1(e) may be misunderstood to require onerous, impractical, vague, or inconsistent verification and documentation requirements that prove unworkable or overly burdensome in practice. That, again, would raise all the flaws identified in the December 2024 Comment. This ambiguity can be resolved, however, by making clear that a pharmacist who verifies, from a notation documented on the prescription itself or other similar communication from the prescriber to the pharmacist, that the prescriber has determined the clinically significant difference of the prescription—and adds a notation to the pharmacist's patient file recording this fact—meets the verification and documentation requirement of Proposed § 1735.1(e).

The Third Modified Text, published on or about February 6, 2025 does not address the ambiguity or flaws identified. The Board should clarify the text of Proposed § 1735.1(e) along the lines proposed above. At a minimum, it should clarify in the preamble of any final action promulgating this rule or in concurrently issued guidance that, under this provision, a pharmacist need only verify and document that a prescribing practitioner has made a finding of clinically significant difference in the manner described above.

Furthermore, to ensure consistent implementation, OFA strongly encourages the California Board of Pharmacy to draft a Frequently Asked Questions (FAQ) document, as previously requested by stakeholders, to address and clarify any potential ambiguities surrounding the verification and documentation requirements. This FAQ will provide critical guidance for both prescribers and pharmacists, helping to prevent misunderstandings and ensuring patients receive safe and effective compounded medications under the new regulatory framework.

We respectfully request that the final regulations be issued with the clarifications requested herein and accompanied by the suggested FAQ document to facilitate seamless compliance and protect patient care.

Respectfully submitted, February 21, 2025

/s/ Victoria Weatherford

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Comments to the California Board Of Pharmacy Regarding
Pending regulations related to pharmacy compounding
Full rule changes link

Shabbir Imber Safdar, Executive Director
Partnership For Safe Medicines

California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste 100
Sacramento, CA 95834

Attn: Lori Martinez
Via Email: PharmacyRulemaking@dca.ca.gov

February 20, 2025

The Partnership For Safe Medicines is a not-for-profit group dedicated to ensuring the security and safety of the U.S. prescription drug supply. We write today to express our grave concerns regarding the proposed rule changes that would:

- remove the review of all adverse drug experiences related to compounded medications; and
- Expand the amount of compounded medications in our drug supply.

This change poses a direct threat to the safety and health of Californians, and we strongly urge you to reject this proposal.

Policy Proposal: Removal of Adverse Event Report requirements

The consequences of eliminating adverse event review

The Board's proposal to eliminate adverse event reporting requirements (sections 1735.11(a)(2), 1735.12(b), 1735.12(c), and 1736.17(a)(2)) presents severe risks, including:

- **Delayed Detection of Drug Safety Issues:** Without a diminished reporting system, it will take longer to identify harmful trends associated with specific medications.

- **Reduced Transparency:** Patients and healthcare providers will have less access to critical safety data that inform medical decision-making.
- **Increased Harm from Compounded Medications:** The absence of adverse event reporting will make it harder to promptly identify and respond to dangerous medications before widespread harm occurs.

A Step Backward in Drug Safety

California has historically been a leader in pharmaceutical regulation and patient protection. Removing adverse drug experience review would reverse this progress, making the state an outlier in drug safety oversight. Regulatory bodies, including the FDA and WHO, emphasize the necessity of adverse event monitoring as a fundamental component of a responsible healthcare system.

The California Board Of Pharmacy should reject this proposed rule change and reiterate the responsibilities of compounders to have a standard operating procedure that requires mandatory reporting of all adverse events promptly.

PSM's concerns with the increasing role of compounded medications in our drug supply chain

Compounded medications fill an important niche role in our drug supply chain.
We have long appreciated the key role that compounding pharmacies play in servicing rare and unmet needs in our drug supply. Helping to fill in the gaps for temporary shortages and providing unique formulations for patients who cannot tolerate the FDA-approved manufactured drug products help fill critical, albeit niche, gaps in America's pharmaceutical supply chain.

Compounded medicines represent a tradeoff of safety versus patient need in our drug supply. As the FDA states,

> [These] unapproved versions do not undergo FDA's review for safety, effectiveness and quality before they are marketed.
>
> ..
>
> A compounded drug might be appropriate if a patient's medical need cannot be met by an FDA-approved drug, or the FDA-approved drug is not commercially available. However, compounded drugs are not FDA approved. This means the agency does not review compounded drugs for safety, effectiveness or quality before they are marketed.
>
> *From FDA alert, "FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss" (12/18/2024)*

Public misconceptions and patient safety risks in taking compounded medications…

While PSM endorses use of compounded medicine as a last resort to fill patient need, in recent years we have seen compounding facilities, medspas, and telehealth companies market compounded medicines to patients even when a commercially-available product was available. Many providers and patients misunderstand that having poor or no insurance is not a qualifying reason to access a compound medication.

Concerned about the lack of knowledge in this area, in September 2024, PSM commissioned one of the only public opinion surveys about Americans' understanding of compounded medications. The findings are an excellent guide for policymakers:

- **90% of Americans are unfamiliar** with compounding pharmacies and the differences between compounded and FDA-approved drugs.
- **75% of Americans mistakenly believe** that compounded medications undergo rigorous FDA scrutiny for safety and effectiveness
- **93% of Americans express concern** upon learning that compounded weight-loss drugs are not FDA-reviewed. Consumers might not be getting the drug they expect.
- **Support for FDA oversight and regulation** has strong bi-partisan backing amongst Democrats (94%), Independents (88%), and Republicans (88%)

...and some providers exploit that lack of knowledge.
We're seeing an unprecedented amount of compounded medication made right now, and much of it is being pitched to Americans without adequate disclosure of the risks. The most egregious example is the recent ad by hims&hers for their compounded GLP-1 medications that ran during the Super Bowl that was viewed by 127 million Americans.[1]

While compounded medications occupy an important niche in our drug supply, some compounders are attempting to expand it beyond this niche. However expanding the role occupied by compounded medications without acknowledging the lower safety profile is devolving the overall safety of our drug supply and endangering Americans.

This standard would be inconsistent with federal law, and endanger patients by placing compounded medicines unapproved by the FDA and with lower safety standards, on the same level as medicines that have been through FDA scrutiny.

Lack of serialization of compounded medicines
All medicines, except compounded medications, must be part of the U.S.'s track and trace system. The expansion of the use of compounded medications will create a large untraceable supply of medicines in our drug supply, and create an opening for criminal behavior. The California Board Of Pharmacy should reject this rule.

In 2013, after a series of major drug counterfeiting incidents that harmed American patients emanated from Florida's drug supply chain, Congress passed the Drug Supply Chain Security Act. The lesson of Florida's

[1] https://www.nielsen.com/news-center/2025/super-bowl-lix-makes-tv-history-with-over-127-million-viewers

endangerment of the U.S. supply chain was that the supply chain required electronic traceability or criminals could easily infiltrate it, as they had shown repeatedly.

At the time, compounded medications were excluded from track-and-trace requirements because the argument was that there was no supply chain and the quantity of compounded medicine in the drug supply was small and rare.

That reality is no longer true. Compounding, particularly outsourcing facilities, have their own trade association, their own funded litigation initiatives to protect their interests, and their products are marketed to the public as a first line therapy. The revenue in this space is now enough to fund Super Bowl ads.

Lack of traceability of compounded medicines is a growing danger to patients.

The Partnership for SAFEMEDICINES.org®

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Policy proposal: expansion of rules regarding which medicines can be compounded

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**
    - The **FDA drug shortage list** is compiled based on rigorous criteria and is overseen by experts responsible for ensuring medication safety and efficacy.
    - Unlike the FDA, ASHP is a respected trade organization but is not a regulatory body. Including its shortage list in determining which 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**
    - Compounded drugs are not FDA-approved, meaning they do not undergo the same stringent review process for safety, efficacy, and quality.
    - 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**
    - 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.
    - 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)**
    - The **DSCSA was enacted to ensure the traceability of medications** and reduce counterfeit drug risks. However, compounded drugs are exempt from its serialization requirements.
    - Expanding compounding eligibility increases the presence of untraceable medications, posing additional risks of counterfeiting, contamination, and supply chain vulnerabilities.
    - 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**
    - 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 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.**

The Partnership for Safe Medicines appreciates the opportunity to provide input on this critical issue. Thank you for your consideration.

Alliance for Pharmacy Compounding

February 21, 2025

Anne Sodegren, Executive Officer
Seung Oh, President
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Subject: *Opposition to the Passage of the Proposed Compounding Regulations*

President Oh, Director Sodegren, and Members of the California State Board of Pharmacy:

The Alliance for Pharmacy Compounding asks that the California State Board of Pharmacy not to pass the proposed compounding regulations as currently written. As stakeholder feedback has indicated, these regulations are just not ready for implementation and there is no buy-in from the healthcare community. A broad coalition of hospital pharmacists, compounding pharmacies, physicians, academic medical centers, and healthcare institutions have consistently raised concerns about the unintended consequences of these rules. Yet, the Board appears poised to move forward without addressing these concerns meaningfully.

We do appreciate the many hours this Board has taken to review iterations of the proposed compounding regulations. Unfortunately, they are still filled with ambiguities and unnecessary obstacles to patient access. We understand the desire to finally pass these regulations and "move on." However, it is of the utmost importance to get these regulations right, as the lives of Californians will be affected. The Board must not – as it appears to be doing – put the expediency of the process ahead of patient access to necessary medications, particularly when the Board has not shown a justification for some of the new rules or indicated how the rules make patients safer.

Additionally, we are troubled that it appears that no written responses to the final round of public comments will be provided before the vote, as has been customary in the past. Instead, the Board intends to include responses in the Final Statement of Reasons, which suggests that the third modified text is functionally the final version—leaving no room for substantive changes before adoption. If that is the case, the Board is prioritizing expediency over stakeholder input and may be violating state administrative procedures rules.

This rulemaking process has not provided a true opportunity for public engagement. The two-minute time slots for public comment, without the ability for follow-up or meaningful discussion, have shut down dialogue and prevented pharmacists from responding to Board members' misunderstandings about the real-world impact of these regulations. A fundamental misunderstanding persists among some Board members regarding USP general chapters and the high standards those chapters already set for patient safety. Members of the Board also have made statements falsely suggesting the availability of

stability studies for the specialized formulations of nebulized medications that are needed by Californians.

The consequences of passing these regulations as written will be harmful to public health. Patients will lose access to critical medications and the care of pharmacists due to overly restrictive and duplicative requirements that go beyond USP standards without improving safety. Critical concerns that remain unresolved include:

- Restrictions on immediate-use compounding that exceed USP standards, unnecessarily limiting access to time-sensitive medications.
- Additional bulk drug testing requirements for Category 1 drugs, which duplicate testing already performed under USP standards, adding unnecessary costs and delays.
- Requiring adherence to guidelines set in USP Chapters above 1000, even though those chapters are not intended for enforcement by USP.

Before finalizing any new rules, we strongly urge the Board to form a task force of pharmacists from community hospitals, academic medical centers, rural hospitals, community pharmacies, and compounding pharmacies to share their expertise. This task force should include USP committee members to provide accurate, real-world insight. This approach would ensure the Board is fully informed before implementing regulations that could disrupt patient care.

The Board must also acknowledge that California's approach to compounding regulation is outdated. USP standards have now set the national benchmark for patient safety while balancing medication access. Rather than layering unnecessary and conflicting state regulations on top of USP standards, the Board should listen to the pharmacists in the profession—who have overwhelmingly opposed these proposed regulations precisely because they go too far and do not make patients safer.

Given these concerns, we urge the Board to enforce existing USP standards in the interim while taking the necessary time to become better informed on the realities of compounding practice. Patients' ability to receive care is at stake, and it is simply too important to rush forward with misguided regulations. Please heed the hundreds of people who have spoken up at previous meetings who have overwhelmingly opposed these regulations.

We strongly urge the Board to reject these regulations and engage in a true, informed dialogue with the healthcare community before proceeding.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer
scott@a4pc.org

PACIFIC RESEARCH INSTITUTE

Tel: 415-989-0833
PO Box 60485
Pasadena, CA 91116
www.pacificresearch.org

February 21, 2025

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste 100, Sacramento, CA 95834
PharmacyRulemaking@dca.ca.gov
Fax: (916) 574-8618

Members of the Board, thank you for the opportunity to submit comments on the California Board of Pharmacy's proposed modifications related to compounded drug preparations, hazardous drugs, and radiopharmaceuticals. We are, respectively, the President and Director of the Center for Medical Economics and Innovation at the Pacific Research Institute. PRI advances free-market policy solutions to pressing public policy issues.

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 post-marketing 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, 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."

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 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.

Thank you for the opportunity to submit these comments.

Best regards,

Sally C. Pipes
President, CEO, and Thomas W. Smith Fellow in Health Care Policy
Pacific Research Institute

Wayne Winegarden, Ph.D.
Sr. Fellow, Business & Economics
Director, Center for Medical Economics and Innovation
Pacific Research Institute

CALIFORNIA MEDICAL ASSOCIATION

February 21, 2025

Lori Martinez
Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
PharmacyRulemaking@dca.ca.gov

Sent via e-mail

RE: Compounded Drug Products Regulations, Third Modified Text Noticed Feb. 06, 2025

Dear Ms. Martinez:

On behalf of our over 50,000 medical student and physician members, the California Medical Association (CMA) submits the following comments on the third modified text of the Board of Pharmacy's (Board) proposed Compounded Drug Products regulations. The Board proposes to amend, repeal, and replace existing regulations, and to adopt new regulations relating to drug compounding.

1. **Language of Proposed Text Conflicts with Board's Description of Its Effect (throughout all sections)**

CMA is disappointed by the Board's continued refusal to revise its proposed language to clarify that the regulations do not apply to physicians. In its response to public comment requesting clarification on whether the regulations apply to physicians and other licensed practitioners, the Board effectively stated the regulations do not apply to licensees of other healing arts boards, noting: "[...] [the] Board's regulations apply to licensees within the Board's jurisdiction. The Board's jurisdiction is limited to those businesses and individuals within its practice act."[1]

The language of the proposed regulations, however, is written in a manner that could be construed to apply to compounding in any setting and by any individual,[2] because their scope is not expressly limited to pharmacists and pharmacies, unlike the current regulation[3]. Thus, the Board's proposed regulations continue to violate the clarity standard of the

[1] Board Jan. 8, 2025 Meeting Materials, Staff Recommended Responses: General Comments, p. 13, https://www.pharmacy.ca.gov/meetings/agendas/2025/25_jan_bd_mat_gen_comm.pdf.
[2] The proposed regulations are generally drafted to apply to the act of compounding, and are not expressly limited to licensees of the Board of Pharmacy. See, e.g., proposed regulation text at § 1735.1 ("[...] the compounding of a CNSP shall meet the following requirements of this article."); § 1735.2 ("[...] the compounding of CNSP shall meet the following requirements of this article."); §§ 1735.3-1735.12 & 1735.14 ("[...] the following requirements apply to nonsterile compounding."); §§ 1736.2-1736.9, 1736.11-1736.20 ("[...] the following requirements apply to sterile compounding."); § 1736.21 ("[...] the following requirements apply to allergenic extracts.").
[3] 16 CCR § 1735(a) (defining "compounding" to mean "activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription").

Administrative Procedure Act because the language of the regulations plainly conflicts with the Board's description of the effect of the regulations.[4]

CMA reiterates its request from CMA's prior comment letter dated December 9, 2024, to revise the proposed regulations to clarify they do not apply to compounding performed by physicians outside of a pharmacy setting, so that the proposed language of the regulations aligns with the Board's description of the effect of the regulations.

2. Requirement to Verify a Preparation Produces a Clinically Significant Difference Interferes with Exercise of Professional Judgment and Exceeds Federal Law (§§ 1735(d), 1735.1(e)(1)(B), 1736(d), 1736.1(e)(1)(B))

CMA 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.[5]

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,[6] 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.[7] Instead, the FDA, in non-binding guidance, recognizes documentation of a prescriber's determination as sufficient.[8] The Board's proposal, by contrast, creates a new obligation

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[4] Gov. Code §§ 11340(b) & 11349.1(a)(3); 1 CCR § 16 (a)(2).
[5] Gov. Code § 11349.1(a)(3); 1 CCR § 16 (a)(2).
[6] Under the doctrine of the separation of powers and hierarchy of law established by the California Constitution, statutes supersede regulations, and a regulation adopted by the executive branch cannot narrow or alter the effect of a statute enacted by the legislative branch, because the State Constitution vests the State Legislature with the power to enact laws. See CAL. CONST. art. III, § 1 (separation of powers); CAL. CONST. art. IV, § 1 (defining legislative power); CAL. CONST. art. V, § 1 (defining executive power); CAL. CONST. art. VI, § 1 (defining judicial power). Accordingly, a regulation could not, and would not, alter or amend a statute or enlarge or impair its scope. *In re Haynes* (2020) 57 Cal. App. 5th 860; *Inzana v. Turlock Irrigation Dist. Bd. of Directors* (2019) 35 Cal.App.5th 429; *Interinsurance Exchange of the Automobile Club v. Superior Court* (2007) 148 Cal.App.4th 1218.
[7] See Food, Drug, and Cosmetics Act § 503A (21 USC § 353a); 21 CFR Part 216.
[8] U.S. Food and Drug Administration, *Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry*, at 8, https://www.fda.gov/media/98973/download.

without clear justification, increasing administrative complexity without improving patient safety.

To enhance clarity and ensure patient's maintain timely access to medications, CMA reiterates its request from our prior comment letter, dated January 27, 2025, to remove "verify and" from proposed sections 1735(d), 1735.1(e)(1)(B), 1736(d), and 1736.1(e)(1)(B) of the third modified text.

Thank you for your consideration. Please feel free to contact me with any questions at (916) 444-5532 or asanchez@cmadocs.org.

Sincerely,

S. Alecia Sanchez
Chief Strategy Officer
California Medical Association

Martinez, Lori@DCA

From: David Burger <David.Burger@sharp.com>

Sent: Friday, February 21, 2025 2:11 PM
To: PharmacyRulemaking@DCA
Subject: In Support of Proposed Language Change

Hello,
I would like to write in and support the Board of Pharmacy change the current language as highlighted below, found in Section 1736.1. Also please see my additional rationale in support of this change below.

Proposed Text Change:

(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:
(i) the prescribing practitioner,
(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 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.

Thank you,

David Burger Pharm D., MSHA
Pharmacy Manager Central Pharmacy Services
(858)627-5650
SHARP Grossmont Hospital

Martinez, Lori@DCA

From: Arlene G <arleneyogini@gmail.com>
Sent: Monday, February 17, 2025 10:13 PM
To: PharmacyRulemaking@DCA
Subject: access to safe and critical Category 1 substances like glutathione, NAD+ and methylcobalamin

Please do not eliminate access to safe and critical Category 1 substances like glutathione, NAD+ and methylcobalamin. These products have been critical to our family's health as we try to recover from multiple rounds of Lyme disease and co-infections and the immunological and neurological issues those diseases cause.

Glutathione is one of the very few substances my damaged body has been able to tolerate and benefit from in my 20+-year Lyme journey. Genetic testing has shown that I cannot make enough on my own and will likely need access to treatment with it for the rest of my days. It's bad enough that we have had to pay out-of-pocket for these substances for over two decades because of America's broken healthcare systems. Please don't take away one of the only things that has helped me keep going.

a. griffin
Santa fe, NM
87501

Martinez, Lori@DCA

From: Alyssa Makowski <alymakjsu@gmail.com>
Sent: Thursday, February 13, 2025 12:51 PM
To: PharmacyRulemaking@DCA
Subject: Stop the BOP

To whom it concerns:
I have been a private family nurse practitioner since 2017, and been in healthcare since 2003. I started my own business in 2021, and realized quickly that many patients are not optimally treated with prescription pharmaceuticals. Typically these are a bandaid for the root cause of the issue, and the patient ends up with more adverse effects and symptomology that needs additional medications.
I began using compounded medications, vitamins, and molecular repair options such as NAD+ and NMN. I saw amazing benefits in my patient population, including patients with neurogenerative disorders, alcoholics, severe cardiovascular and neurovascular disease. Without these options, these patients typically require hospitalization, infusions of iron, antibiotics, experience severe infections sometimes leading to death. And even mild cases of patients that experience chronic fatigue, depression and anxiety, and obesity have greatly improved their health and wellness. This impacts not only their day to day, but their ability to show up to work, show up in their community, and be present for their families.
Taking these options away for patients would be like shooting them in the foot and expecting them to continue to walk at their usual pace. It's just not possible.
I strongly advise the Board of Pharmacy in California to allow these options to be produced, manufactured, and shipped into the state, to prevent increasing morbidity, mortality, and even the exodus of patients leaving the state permanently or going to other states or countries to obtain their healthcare.

Thank you for your consideration,
Well by AM Nursing, Inc. CEO/Owner
Aly Johnston, FNP-BC

Be well, and always choose gratitude

Sent from my iPhone

Martinez, Lori@DCA

From: Barbara Mockus <bmockus@icloud.com>
Sent: Saturday, February 15, 2025 1:05 PM
To: PharmacyRulemaking@DCA
Subject: Glutathione, NAC and more

Please stop creating bureaucracy and roadblocks that will change patients ability to CHOOSE for their own health and access these medications at prices we can afford. As a Lyme disease and co-infection patient, these medications help me keep functioning. Without them, my quality of life will dramatically fail. There are so many areas of healthcare where we need to increase access, not reduce it. Please don't add to this problem. Please do not further regulate or restrict our access to the point where manufacturers and pharmacies will cease to make these items available. They are life sustaining for us.
Thank you.
Barb Mockus

Sent from my iPhone

Martinez, Lori@DCA

From: cassandra1444@verizon.net
Sent: Saturday, February 15, 2025 1:24 PM
To: PharmacyRulemaking@DCA
Subject: Public Comment on Title 16 CCR Sections 1735-1738

Hello.

I got Lyme Disease during a hike in S. California in 1996. I got the bull's eye rash, but the approved medical blood test came back negative.

With continually worsening health, I finally got TWO tests in 2005 that confirmed I did have Lyme Disease.

Short-term antibiotics were obviously no longer applicable. I started having Grand Mal seizures in 2007.

It has been a long and expensive journey back to functionality, which involved many different alternative therapies.

Do not cut off people from treatments that actually work.

Best,

Cassandra Auerbach

Martinez, Lori@DCA

From: Carmen Miller <carmenmiller40@icloud.com>
Sent: Sunday, February 16, 2025 11:04 AM
To: PharmacyRulemaking@DCA
Subject: Gludithione shots and I'v

I am a patient and theses are my treatment and to be dented this is not fair to me they are a good send thank you Carmen. Miller of Maine
Sent from my iPhone

Martinez, Lori@DCA

From: Cyndi Orr <fly.with.new.wings@gmail.com>
Sent: Saturday, February 15, 2025 6:43 PM
To: PharmacyRulemaking@DCA
Subject: Glutathione

To whom it may concern:

Please do not restrict patients' access to glutathione and other modes of detoxing! When I had Lyme disease, I infused some on a daily basis, thank God, and it helped tremendously. People who are fighting toxins of any kind need access to these treatments in order to support their bodies' fight to get rid of them and take the burden off their system.

Thank you,

Cyndi Orr
Sent from my iPad

Martinez, Lori@DCA

From: Carol Weis <carol.weis07@gmail.com>
Sent: Saturday, February 15, 2025 9:49 AM
To: PharmacyRulemaking@DCA
Subject: Glutathione

I was diagnosed with Chronic Lyme and Bartonella in 2017. Since that time I have received Glutathione in all its forms with potentially live saving results.
After experiencing both cognitive and memory impairments I became disabled from my career as a Masters Prepared RN. I subsequently received IV antibiotics which significantly caused elevated liver enzymes to alarming levels. Glutathione allowed me to continue my antibiotic therapy by normalizing my liver function.
Since completing my IV antibiotics, I now take oral antibiotics on an intermittent basis when my cognitive function begins to once again decline. During these periods; usually twice each year, I also take glutathione supplements orally or topically. Additionally I receive IV glutathione with positive results within just a few days. My mind clears and my memory rebuilds itself. I become "me" again.
I rely on my infusions of glutathione to help me regain the part of me that has been lost to this horrible chronic and life altering disease.
Please do not remove Glutathione. Like so many others, I value it. Glutathione has saved my life.

Carol Weis

Martinez, Lori@DCA

From: Pamdal Nicholas <pamdalnicholas@gmail.com>
Sent: Wednesday, February 19, 2025 11:08 PM
To: PharmacyRulemaking@DCA
Subject: Public Comment on Title 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

I'd like to ask that you please reconsider the proposed regulations that would severely limit access to critical sterile compounded medications like injected and nebulized glutathione, methylcobalamin, NAD+, and others. These treatments are essential for many, including firefighters and chronic illness patients such as my wife, who counts on them to live an unencumbered life.

During the February 5, 2025 meeting, board members briefly considered the possibility of pulling out the part of these regulations that was causing the most stir with people, and I'm begging you to consider that option, if you can not outright reject these new regulations in full.

Thank you for taking the time to listen to input on this urgent matter. I am praying that you make the best choice for public health and patient access, and engendering a trust among the thousands that have spoken up and made their voice heard that this system works, and that you work for the people of California.

Sincerely,
David Nicholas
pamdalnicholas@gmail.com
116 Amber Way,
Livermore CA 94550

Martinez, Lori@DCA

From: Janet Boren <borenjanet108@gmail.com>
Sent: Monday, February 17, 2025 4:21 AM
To: PharmacyRulemaking@DCA
Subject: To whom this may concern.

I am absolutely against the banning of any natural medicine and specifically glutathione. Taking Glutathione will destroy live ,if not kill those who desperately need it like firefighters, but there are thousands of people who need glutathione for their health. That you eould be taking away a life saving medicine from.
.please , do not do this. We, the people call on you to save lives, not destroy thrm

Martinez, Lori@DCA

From: sjacql@aol.com
Sent: Friday, February 14, 2025 10:00 AM
To: PharmacyRulemaking@DCA
Subject: Access to glutathione, B12 and other compounds

Hello,
I have multiple, rare chronic illnesses. Some of my only good days are because of compounded intravenous things like glutathione, b12 and other b vitamins that I have to pay for, gladly, to have a bit of my health back.

Please, I beg of you do not take these things away. If my health gets any worse I don't know what point there is for me to stay alive. These compounds give me the health and hope I need to continue.

Sincerely,
Jacqlyn Smith

Martinez, Lori@DCA

From: Lisa Linton <owdogmom@outlook.com>
Sent: Monday, February 17, 2025 10:26 AM
To: PharmacyRulemaking@DCA
Subject: Attention Lori Martinez-Concerns About Title 16 CCR Sections 1735-1738

Dear Ms. Martinez,

I am writing to you as a concerned California voter against the proposed regulations in sections 1735-1738 which would severely limit access to widely used Category 1 sterile compounds like glutathione and methyl B12, available in the rest of the USA. I have Neuro Lyme Disease and I struggle to write and read so my comments will be brief. However I would like to reference a letter you received from Stop The Bop that better states why these compounds are critical to survival for so many Californians. I know for myself in finding the right treatment for my Lyme Disease, my doctors need to know that they have access to these compounds whenever they feel they're needed in my treatment plan as do the doctors of Long COVID patients, firefighters that just fought the Palisades and Eaton fires and thousands of other California patients for whom these drugs are their hope to better health or even a cure. Please, please do not cut off access to these compounds or the compounding pharmacies that provide access to these critical drugs. They are widely available across the rest of the United States so it seems if California wants to be seen as a shining example to the rest of the US of how to live a healthy lifestyle the state needs to make sure access to these compounds is available to some of its sickest patients. Without it there will be patients with diseases or illnesses similar to mine who will never be able to live a healthy life again. In 2025 it is totally unacceptable to ban safe and studied compounds that can heal people.

Thank you for taking time to read this.

Sincerely,
Lisa Linton

Martinez, Lori@DCA

From: Lilach Mendelovich <lilachmucla@gmail.com>
Sent: Wednesday, February 19, 2025 9:32 PM
To: PharmacyRulemaking@DCA
Subject: Public Comment on Title 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

I am writing, as someone who needs glutathione to treat my chronic illness, to express strong opposition to the proposed regulations that would severely limit access to critical sterile compounded medications like injected and nebulized glutathione, methylcobalamin, NAD+, etc. and urge you to adopt member Nicole Thibeau's practical suggestion to carve out this section about Category 1 bulk compounds from the larger regulation package.

At the February 5, 2025 board meeting, multiple members had deep concerns about this section having devastating impacts on the health and lives of Californians. Members Hughes and Thibeau both agreed it is "not ready for primetime", and yet it seemed that the focus of the board remained on passing the entire rules package before the deadline you are up against.

PLEASE do not let bureaucratic deadlines be prioritized ahead of people's health! The only ethical decision is to remove Sections 1735-1738 before you pass the rest of the regulations and take it back to the drawing board.

These treatments are essential for many, including firefighters and chronic illness patients like me, and the regulations would create unnecessary barriers that harm the healthcare system, businesses, and people of California. Despite this, your proposal introduces extreme testing requirements that far exceed federal standards without any adequate safety-based justification.

The unfeasible financial burden these regulations would place on pharmacies is a critical concern. Member Serpa's cost estimates—$16.10 per glutathione vial and $8.06 per methylcobalamin vial—dramatically understated the actual costs of stability testing. These tests actually range from $10,000 to $30,000 per API. These prohibitively expensive tests would force pharmacies to discontinue offering most if not all formulations of these treatments, eliminating access to life-saving medications.

The need for treatments like nebulized glutathione is more urgent than ever since southern California's severe Urban-Wildfires released record levels of harmful toxins like lead and asbestos into the environment. Restricting access to these treatments would escalate health risks, including fatal cancers, for first responders, vulnerable residents, and future generations.

The public opposition to these regulations is overwhelming, with over 11,000 signatures on a petition—with an estimated 1,000+ from California firefighters—and hundreds of pages of comments submitted in writing and in person over the past year.
I was one of the people who attended the entire Feb 5th meeting in order to speak about my life changing treatment with glutathione. I found the format very frustrating since there was no way for both sides to have a real conversation.

This was very clear when board members were confused or had questions about testimony that was given by a doctor IN the room and they did not ask her to come back to the microphone and answer their questions.
In general there was a lot of confusion and conflicting information, it was clear that most board members aren't sure what unintended consequences these regulations could have, even as doctors and patients alike are testifying to the real and devastating impacts of these regulations - some of which are already happening, whether intended or not.

All of this demonstrated a clear need for further discussion and real conversation between the board and stakeholders about sections 1735-1738.
With such high stakes the board has a moral obligation to take the time to get these rules right.
Rushing the process at this moment in time is particularly harmful since member Serpa said the BOP is trying to enforce FDA rules - but federal agencies are being completely reshaped as we speak by this current administration. We shouldn't rush to set rules in stone that might not even exist federally in a few months.

As written, the proposal creates unnecessary barriers that will severely limit access to life-saving treatments. These barriers create an unjustifiable financial burden on patients and pharmacies and fail to reflect the true costs and needs of the community. I strongly urge The Board of Pharmacy to either (a) withdraw 1735-1738 entirely, or (b) send these proposed regulations back to committee and re-write them to align them with and not exceed federal and Pharmacopeia standards by making the following changes:

* Adhere to USP by allowing Category 2 compounding without requiring full stability studies, provided sterility and endotoxin testing is performed and a reasonable beyond-use-date (e.g., 45 days refrigerated) is applied.
* Eliminate adherence to USP Chapters above 1000, which are not enforceable requirements and are meant for informational purposes only.
* Amend the language to specify that Title 16 compounding regulations apply only to pharmacists. As written, this board appears to begin regulating medical practices which is regulatory overreach.
* Remove the requirement of additional documentation of "clinical circumstances" which is not required by the FDA.

Thank you for your time and attention to this urgent matter. I trust you will act in the best interest of public health and patient access.

Sincerely,

Lilach Mendelovich

Martinez, Lori@DCA

From: Lauren Vorhees <laurenvorhees@gmail.com>
Sent: Sunday, February 16, 2025 10:36 AM
To: PharmacyRulemaking@DCA
Subject: Please do not restrict!!Title 16 CCR 1735-1738

Re: title 16 CCR 1735-1738

Please please please please do NOT restrict lifesaving compounds such as glutathione and methyl b12 in California. I need these compounds regularly to address chronic Lyme disease and genetic issues. I need all the help I can get, and there are many others like me. Please do not add more chaos into a medical system that already fails me.

Lauren (Shelly) Vorhees
Laurenvorhees@gmail.com

Martinez, Lori@DCA

From: Monique Millon <mb.millon@gmail.com>
Sent: Friday, February 14, 2025 6:36 AM
To: PharmacyRulemaking@DCA
Cc: Monique Millon
Subject: Glutathione

Hello

I want you to know that my son would be dead by now if it were not for his IV glutathione.

Please do not make it impossible to get .

This would be a crime against humanity.

Thanks and Best regards

Monique Millon
Cell 602 769 9949

Martinez, Lori@DCA

From: Marjorie Morgenstern <mmorgenstern@ci.cloverdale.ca.us>
Sent: Sunday, February 16, 2025 10:39 AM
To: PharmacyRulemaking@DCA
Subject: Public Comment on Proposed Amendments to Title 16 CCR Sections 1735-1738

February 16, 2025

Public Comment on Proposed Amendments to Title 16 CCR Sections 1735-1738

Dear Members of the California State Board of Pharmacy,

Please start actually listening to and paying attention to the public's comments about Category 1 Sterile Compounds. It appears that only three board members are actually listening to public comments. The rest of the board appears to be married to their own old tired biased agenda. As a local elected official I find it extremely disappointing that public comments from Pharmacists, Medical Doctors, Veterinarian's, Firefighters, Lyme Disease and Chronic Fatigue Patients and any other patient that has found using Category. 1 Sterile Compounds helpful for treatment are not being listened to and respected.

We do not need stricter regulations on Category 1 Sterile Compounds. The fact that so many of the board members are ignoring public comments is beyond disturbing and lacks integrity. I have contacted both of my Assemblymembers' offices to inform my Assemblymembers that the public's comments are being ignored. Please stop the farce and listen to the good people of California and then act accordingly. You are suppose to actually listen to public comment and to represent the residents of California. So far only three board members are actually listening.

I personally have found compounded Glutathione and B12 extremely helpful for treating Lyme Disease. Do not make it harder for Lyme Patients who are already suffering enough to receive treatment. Many of us are living in poverty after spending thousands of dollars attempting to get well. We do not need any added hardships inflicted on us from a board with their own agenda.

The proposed amendments to Title 16 of the California Code of Regulations, Sections 1735-1738, impose unnecessary restrictions on access to Category 1 sterile compounds, such as glutathione, methylcobalamin, and NAD+. These regulations, as currently written, will devastate patient access to life-saving treatments in California, despite no evidence of safety risks warranting such measures.
In the wake of the Palisades and Eaton fires, Californians are grappling with the health consequences of prolonged toxic smoke inhalation, including toxin buildup in lung tissue. For many, the only effective treatment to address these toxins is nebulized and intravenous glutathione. These therapies are utilized by firefighters, Lyme Disease and Long COVID patients, and individuals with conditions like ME/CFS and methylation impairment. Denying access to these critical treatments endangers vulnerable populations and ignores the unique health challenges faced by our state.

USP does not require full stability studies for Category 1 or 2 sterile compounding. These requirements only apply to Category 3 compounding. For the Board to mandate such studies—which can cost $10,000 to $30,000 per formulation—imposes an insurmountable financial burden on pharmacies. This will force them to

limit offerings to the most generic formulations, eliminating the ability to create customized treatments based on individual prescriber orders.

Sincerely,

City of Cloverdale Councilmember Marjorie Morgenstern

Sent from my iPad

Martinez, Lori@DCA

From: nichole serocki <nicholeserocki@gmail.com>
Sent: Sunday, February 16, 2025 1:21 AM
To: PharmacyRulemaking@DCA
Subject: Glutathione, B-12 IV's were key to my recovery from my illness

Dear Board,

Do NOT restrict this tried and true effective treatment which I used personally under the supervision of Dr. C. Martinez years ago. After nothing else was working in my serious debilitating illness, this is what gave me my life back, and was a turning point that showed me I could recover and not stay bed ridden.

It was effective, and did it job, where later I no longer needed them and recovered - without it, I don't know if I would be here today.

PLEASE do not restrict what I and many other patients have know for over 12 years for me - it works, it did no harm and it gave my body the ability to recover from a devastating illness.

I had gone to many a dr in San Diego before I found Dr. Martinez MD and her decision to use the IV Glutathione therapy, and a couple other items gave me my life back.

It likely saved the system thousands because it was EFFECTIVE and gave my body what it needed to recover.

There is no reason after years of safety and efficacy to remove this from patients. It is wrong to take this away and why would you want to reverse what patients have found helped them get their lives back, like me.

Sincerely,
Nicholette Serocki\
Registered Voter
El Cajon, CA

Martinez, Lori@DCA

From: Peter Pitts <ppitts@cmpi.org>
Sent: Friday, February 14, 2025 11:54 AM
To: PharmacyRulemaking@DCA
Subject: Attn: Lori Martinez -- proposed additional modifications to Title 16 CCR Sections 1735 et seq, 1736 et seq, 1737 et seq, and 1738

Per proposed additional modifications to Title 16 CCR Sections 1735 et seq, 1736 et seq, 1737 et seq, and 1738 et seq Related to Compounded Drug Preparations, Hazardous Drugs and Radiopharmaceuticals:

Hello Lori:

My name is Peter Pitts. I am the President of the Center for Medicine in the Public Interest (www.cmpi.org) and a former Associate Commissioner at the FDA. I write to you to weigh in on the issue of drug compounding — and particularly the compounding of GLP-1 agonist products. I know you are likely to be inundated with comments on this issue, so I will be as consist possible.

A few key points:

* These products are illegal and unregulated. Caveat emptor is bad healthcare policy.

* The advertising and marketing of these products are also illegal.

* There is a difference between drug compounders and companies running illegal pharmaceutical manufacturing operations.

* Not stridently working to stop these illegal drug manufacturers is an open invitation to counterfeiters.

* Playing Russian Roulette with the lives of Californians is unacceptable.

Below are a few articles (by me) that support all of the above statements — and more.

https://www.washingtontimes.com/news/2024/sep/5/compounders-of-drugs-that-fight-diabetes-obesity-s/

https://www.washingtontimes.com/news/2024/sep/19/weight-loss-confusion-lets-not-compound-problem/

https://www.washingtontimes.com/news/2024/feb/12/redlining-americas-girth-new-medicines-help-battle/

Thank you for your time and consideration. Please let me know if there are any questions you would like to discuss in greater detail.

Kind regards,

Peter

Martinez, Lori@DCA

From:	Doctor Horowitz <Dr.Horowitz@hvhac.com>
Sent:	Friday, February 14, 2025 5:25 AM
To:	PharmacyRulemaking@DCA
Cc:	Medical
Subject:	Do not restrict glutathione access and other compounded medications to those who desperately need it

Dear Sir/Madame,

I am board certified internist with 41 years of experience, who regularly uses compounded medication by excellent licensed pharmacists. Glutathione is part and parcel of the 9-week oral antibiotic protocol using dapsone combination therapy (see the articles below) which helps to lower methemoglobin levels, support detoxification and lower Herxheimer reactions by blocking NFKappa B during Lyme treatment. It has also been essential in protecting patients from the effects of COVID-19. I published the first article in the world medical literature on the use of GSH in COVID-19 in April 2020 and not one of my patients died during the pandemic using higher dose GSH helped decrease oxidative stress (and the virus needs to lower GSH to replicate).

Horowitz, R.I., Freeman P, Bruzzese, J. Efficacy of glutathione therapy in relieving dyspnea associated with COVID-19 pneumonia: A report of 2 cases. Respiratory Medicine Case Reports, April 21, 2020. Article Number: 101063 https://doi.org/10.1016/j.rmcr.2020.101063

Along with compounded glutathione, some of my patients require compounded B12 and other medication because of chemical sensitivity and mast cell activation. They can not live without them.

Please do not restrict these essential compounded medications which are life saving in my patient population.

Thank you for your attention to this matter.

Sincerely,

Rich Horowitz MD

Member HHS TBDWG 2017-2019

Co-chair HHS Co-infections and Other Tickborne Diseases Subcommittee 2017-2019

Member, HHS Babesia and Co-infections Subcommittee 2020

Member NYS Dept of Health TBDWG 2021-2024
Board certified Internal Medicine
Medical Director Hudson Valley Healing Arts Center

Dapsone documentary:
https://players.brightcove.net/6314452011001/PAMDt93Yi_default/index.html?videoId=6353288590112

10 Dapsone Articles on The Effective Treatment of Chronic LD & Associated Co-infections Including Bartonella: As of May 11, 2024

Horowitz, R.I.; Fallon, J.; Freeman, P.R. Combining Double-Dose and High-Dose Pulsed Dapsone Combination Therapy for Chronic Lyme Disease/Post-Treatment Lyme Disease Syndrome and Co-Infections, Including Bartonella: A Report of 3 Cases and a Literature Review. *Microorganisms* **2024**, *12*, 909. https://doi.org/10.3390/microorganisms12050909

Horowitz, R.I.; Fallon, J.; Freeman, P.R. Comparison of the Efficacy of Longer versus Shorter Pulsed High Dose Dapsone Combination Therapy in the Treatment of Chronic Lyme Disease/Post Treatment Lyme Disease Syndrome with Bartonellosis and Associated Coinfections. *Microorganisms* **2023**, *11*, 2301. https://doi.org/10.3390/microorganisms11092301

Horowitz RI, Freeman PR. Efficacy of Short-Term High Dose Pulsed Dapsone Combination Therapy in the Treatment of Chronic Lyme Disease/Post-Treatment Lyme Disease Syndrome (PTLDS) and Associated Co-Infections: A Report of Three Cases and Literature Review. *Antibiotics*. 2022; 11(7):912. https://doi.org/10.3390/antibiotics11070912 https://www.mdpi.com/2079-6382/11/7/912/htm

Horowitz, R.I.; Freeman, P.R. Efficacy of Double-Dose Dapsone Combination Therapy in the Treatment of Chronic Lyme Disease/Post-Treatment Lyme Disease Syndrome (PTLDS) and Associated Co-infections: A Report of Three Cases and Retrospective Chart Review. *Antibiotics* **2020**, 9, 725. https://doi.org/10.3390/antibiotics9110725

Horowitz, R.I., Murali, K., Gaur, G. et al. Effect of dapsone alone and in combination with intracellular antibiotics against the biofilm form of B. burgdorferi. BMC Res Notes 13, 455 (2020). https://doi.org/10.1186/s13104-020-05298-6 https://bmcresnotes.biomedcentral.com/articles/10.1186/s13104-020-05298-6?fbclid=IwAR0qt8lyjHfOYlC_Z5k_a4DGxa49sYned_6xC8mRz66m2Wirekb0MX0vBRA#citeas

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Tardo AC, McDaniel CE and Embers ME (2023). Superior efficacy of combination antibiotic therapy versus monotherapy in a mouse model of Lyme disease. Front. Microbiol. 14:1293300. doi: 10.3389/fmicb.2023.1293300

https://www.frontiersin.org/articles/10.3389/fmicb.2023.1293300/full

Martinez, Lori@DCA

From: Raylon Smith <raylonspcb@gmail.com>
Sent: Friday, February 14, 2025 9:33 AM
To: PharmacyRulemaking@DCA
Subject: Rule changes impacting Category 1 sterile compounds

Regarding potential new hurdles or restrictions to safe and effective compounds such as NAD+, Glutathione, and B-12

These compounds (using trusted compounding pharmacies like Infuserve) have proven a critical leg in the care of loved ones.

Please do not restrict them further as many Californians/Americans will suffer even more than they are under a complex and frustrating system.

Regards,
Raylon Smith
Sunnyvale CA

Martinez, Lori@DCA

From: SG <meddoc06@yahoo.com>
Sent: Wednesday, February 19, 2025 8:11 PM
To: PharmacyRulemaking@DCA
Subject: Public Comment on Title 16 CCR Sections 1735-1738

Stephan Gevorkian
11143 Mountcastle Drive
Studio city CA 91604
11143mount@gmail.com
323-804-3000
2/18/2025

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Subject: Strong Opposition to the Proposed Ban on Compounded NAD, Glutathione, B12, and Other Essential Compounds

Dear Members of the California State Board of Pharmacy,

I am writing to express my strong opposition to the proposed ban on the compounding of NAD, glutathione, B12, and other essential compounds under Title 16 CCR Sections 1735-1738. This proposal is an unnecessary and harmful restriction that will have serious consequences for patients, healthcare providers, and the advancement of medical treatment.

Compounded therapies are a critical component of individualized patient care, offering solutions that cannot be met by standard pharmaceuticals. NAD, glutathione, and B12 are used in a variety of medical applications, including neurological support, immune function, metabolic health, and chronic disease management. Banning these compounds from compounding pharmacies will deprive patients of access to safe, effective, and often life-changing treatments.

The proposed ban undermines the medical autonomy of licensed healthcare professionals who rely on compounding to provide personalized treatment plans for their patients. Many individuals depend on compounded formulations because commercially available alternatives are inadequate, inaccessible, or do not meet their specific medical needs. Without these options, patients will be left with fewer choices, leading to worsened health outcomes, increased healthcare costs, and the potential need to seek care outside of California.

There is no substantial evidence that compounding these substances poses a widespread public health risk when performed by licensed professionals following appropriate guidelines. Instead of imposing an outright ban, the Board should focus on maintaining high standards for compounding safety, ensuring that patients continue to have access to these vital compounds while upholding quality and regulatory oversight.

This ban does not serve the best interests of the public or the medical community. It disregards the scientific basis for these treatments, the needs of thousands of patients, and the role of physicians, naturopathic doctors, and other licensed providers who prescribe these compounds responsibly. The Board should consider the real-world impact of such a decision and recognize that compounding is an essential practice that supports patient health in ways that standard pharmaceuticals cannot.

I urge you to reject this proposal and work toward policies that protect patient access to necessary treatments without imposing blanket prohibitions that will do more harm than good. Patients and healthcare providers should not have to fight for access to well-established and beneficial therapies. I strongly encourage the Board to reconsider this approach and prioritize solutions that enhance safety without eliminating access to vital medical care.

Sincerely,
Stephan Gevorkian

To: PharmacyRulemaking@dca.ca.gov
Re: Public Comment on Title 16 CCR Sections 1735-1738

February 20, 2025

To the California Board of Pharmacy,

I am submitting this comment in strong opposition to the proposed regulations on sterile compounding, particularly those that would severely limit access to critical compounded medications, including nebulized glutathione, methylcobalamin, NAD+, and other necessary treatments. These treatments are essential for thousands of patients across the state—especially those suffering from chronic conditions such as ME/CFS, Long COVID, and for firefighters exposed to toxins in the line of duty.

The key issue with the proposed regulations is the financial burden they place on pharmacies, making the continued availability of these life-saving medications effectively unsustainable. Stability studies, which are required by these new regulations, are costing between $10,000 and $30,000 per formulation, with some common combinations potentially costing upwards of $90,000 to comply. These costs are prohibitively expensive for many pharmacies, especially smaller ones that rely on compounding customized medications for their patients.

To be clear, these stability studies are not required under current FDA or USP guidelines for many of the substances in question. As Maria Serpa correctly noted in her statement, the FDA's Category 1 list of approved bulk substances already ensures these treatments are safe and can be compounded without the need for additional studies. However, the proposed regulations introduce additional stability study requirements and documentation, making compliance financially unfeasible for many compounding pharmacies.

Serpa's assertion that these regulations merely reflect federal and USP guidelines is misleading. She stated that "nothing in here says that each and every pharmacy needs to test all of these things for each and every compound," but this does not reflect the reality of the regulations as they are written. These rules will require many pharmacies to perform tests they are not currently required to under federal standards. This will raise the cost of these medications, making them inaccessible to patients who rely on them, despite the FDA and USP guidelines already providing a clear pathway for their safe use without such additional regulatory burdens.

For example, Section 1736.9 of the proposed regulations introduces requirements for stability testing that exceed USP <797> standards. The FDA 503A guidelines permit the use of published, reputable stability data from manufacturers or other sources, and USP <797> similarly does not mandate in-house stability studies for substances like glutathione and NAD+. These proposed additional testing requirements create a financial barrier that will result in reduced availability of these medications, despite their long-established safety in compounded formulations.

The Board has failed to provide compelling evidence to justify the proposed regulations. The November 2024 education session was biased and misleading, with none of the examples presented being relevant to the current circumstances. Despite clear objections from the public,

including on the day of the presentation, the Board continues to reference this session as a necessary source of information for the public and fellow Board members to shape and justify these proposed regulations. This ongoing reliance on inaccurate and unsubstantiated information undermines the credibility of the regulatory process.

I also want to address the impact this will have on public health, particularly during California's ongoing wildfire crisis. As we know, toxic smoke and particulate matter released by wildfires severely impact respiratory health, especially for vulnerable individuals. Research has shown that nebulized glutathione has a protective effect against harmful toxins like hydrogen cyanide, benzene, and polycyclic aromatic hydrocarbons released by wildfires. This is especially relevant as many individuals who are already battling the health impacts of long-term exposure to environmental toxins—such as first responders and people with compromised respiratory health—rely on treatments like nebulized glutathione to protect their lungs and reduce exposure to harmful substances. Denying access to treatments like this will undoubtedly harm those most at risk.

Moreover, the recent decision by the National Institutes of Health (NIH) to limit indirect costs for research institutions—capping them at just 15%—has serious implications for the future of medical research. These cuts reduce the ability of universities and research organizations, including those in California, to conduct critical research that could lead to FDA-approved treatments for conditions like ME/CFS, Long COVID, and other chronic illnesses. NIH cuts threaten the infrastructure that supports studies on vital treatments, and without FDA-approved therapies for these conditions, compounded treatments remain one of the few viable options. The proposed regulatory burdens on pharmacies add further barriers to accessing these treatments, exacerbating the risk for patients who have no other options.

Indirect costs are essential for covering the basic infrastructure of research—everything from lab space and equipment to the salaries of the support staff who make these studies possible. By limiting this funding, NIH is essentially cutting the financial foundation necessary to conduct any significant research, including the kind of research that could lead to FDA-approved treatments for conditions like ME/CFS, Long COVID, and others that are currently underserved by existing treatments.

In the absence of FDA-approved treatments for these conditions, researchers in California and across the nation have been working tirelessly to explore alternatives, including compounded medications like nebulized glutathione, methylcobalamin, and NAD+. However, with these severe cuts to research funding and regulatory barriers created by the proposed California regulations, these treatments—often essential for patients with chronic illnesses—will become increasingly difficult to access. This is a direct threat to patient health, particularly as more people with conditions like ME/CFS and Long COVID struggle to find effective care.

These cuts and proposed regulatory hurdles are a public health crisis in the making. Research into these critical treatments, especially as California faces the ongoing risk of wildfire smoke and the environmental toxins that accompany it, is essential for safeguarding vulnerable populations. The increasing financial burden on pharmacies due to unnecessary regulatory requirements only further exacerbates the issue, making it less likely that patients will have access to the compounded treatments they need.

On a personal note, my own experience underscores the urgency of this issue, the restriction of doctor-patient autonomy, and limiting interference in healthcare options. My primary care doctor, an osteopathic family medicine specialist at a large, multi-site practice, has been administering IVs with NAD+, glutathione, and Vitamin C with significant improvement in my symptoms. Given the severity of my medical condition, it is extremely difficult for me to leave the house to receive treatments in-office twice a week. The post-exertional malaise (PEM) I experience from such physical exertion makes it necessary for me to manage my energy very carefully and within a restricted "energy envelope." These trips, which require dressing, bathing, and traveling to the office, contribute to my symptom flare-ups and are simply unsustainable.

My doctor has agreed that continuing this therapy at home with compounded medications would be the most practical solution, yet it is exceedingly difficult to find a pharmacy that will provide or ship these compounded treatments due to the burdensome and overly restrictive regulatory environment. It seems that pharmacies are already being forced to adhere to requirements that go beyond federal guidelines—requirements that appear to be both unnecessary and damaging. These limits patients like me from accessing treatments that provide tangible benefits, despite the widespread medical need for these therapies.

In addition to the challenges facing patients like me, I want to highlight an issue that has been exacerbated by the current regulatory environment in California. AgelessRx, a well-known telemedicine provider, has been forced to stop shipping vials of NAD+ and glutathione to California patients due to these underground regulations. AgelessRx had previously provided these treatments to patients in California without issue, but as the harmful nature of these regulations and the punitive actions taken against compounding pharmacies have gained wider recognition, they ceased shipping these life-saving medications to the state. This is a clear example of how these regulations are not only overreach but are actively harming patient access to therapies that many of us rely on. Patients in California, including those with ME/CFS, Long COVID, and other chronic conditions, are now left without a viable option for obtaining these essential treatments.

Furthermore, Simmaron Research, a prestigious ME/CFS research clinic, has partnered with AgelessRx to advance a groundbreaking clinical trial investigating the efficacy of Low-Dose Rapamycin in treating ME/CFS, Long COVID, and other infection-associated chronic conditions. This collaboration aims to leverage AgelessRx's expertise in decentralized clinical trials to enhance patient access and streamline the study process. Early trials suggest that Low-Dose Rapamycin has the potential to induce remission in ME/CFS patients, with significant improvement in symptoms such as post-exertional malaise (PEM) and fatigue. According to a study by Dr. Montoya and others published on Health Rising (2022), Rapamycin shows significant promise in improving chronic fatigue symptoms. Furthermore, PolyBio.org's ongoing Long COVID clinical trial on Low-Dose Rapamycin points to substantial potential for symptom relief in long-term COVID patients, showcasing the drug's capacity to modify immune response and treat chronic fatigue-related conditions.

However, the restrictive and punitive regulations in California have created an environment where compounding pharmacies are unable to provide these essential treatments. The increasing recognition of the damaging nature of these regulations has led to limited access to life-saving

therapies for Californians. This restriction creates a clear and dangerous gap in the availability of treatments for patients who are already struggling to find effective care.

I applaud and highlight the statements made by Members Trevor Chandler, Jeff Hughes, and Dr. Nicole Thibeau, who have intelligently, thoughtfully, compassionately, and appropriately expressed support for expanding patient access to these critical treatments.

Member Chandler demonstrated wisdom and applied his insight from years of grassroots advocacy, "Responses like this are not false; they are not to be disregarded. The voices we have heard deserve to be taken seriously, and they deserve to be given the respect of showing that the effort they did to have their voices heard at this meeting and advocate to us are taken as seriously as possible."

Member Hughes demonstrated compassionate and forward-thinking advocacy on behalf of disabled individuals, firefighters, first responders, and those impacted by urban-wildland fires. Jeff Hughes' remarks, "There are hundreds, if not thousands, of people using these compounded medications across the state", reflect the reality of the wide-reaching need for these treatments. His comments underscore the urgent need for thoughtful, immediate action as this crisis intensifies in Los Angeles and across California. The world is watching how public health bodies will respond to this growing climate and environmental emergency.

Additionally, Dr. Nicole Thibeau demonstrated vulnerability and the unmatched wisdom of lived experience. She highlighted the potential harm these regulations could cause. Her pointed question (whether these regulations could inadvertently create greater risks by limiting access to necessary treatments) reminds us that people will find ways to access critical medical care, whether it's for abortion or for treating conditions like Long COVID and ME/CFS, which currently lack FDA-approved treatments. And let's not forget that 5% of all ME/CFS patients complete suicide due to the unbearable suffering of the condition. Access to sterile compounds like GLP-1s, especially in times of shortage, saves lives and has been demonstrated to reduce risk and ideation of suicide.

In July, Dr. Nicole Thibeau was moved by the outpouring of personal pleas from people with Long Covid and ME/CFS and urged, "People with chronic illnesses and disabilities are always an afterthought. And I'm encouraging us to reposition that as being one of our main focuses." She also very clearly said, "We're causing more harm if we take away treatments from people who have diseases that don't have any approved treatment." She reminded the entire board and the public that, "And if we take away tools that are helping them and protecting them, I can't feel like we're meeting our mission." These are the voices that must guide this decision-making process.

Shockingly, today we're fighting to maintain our very existence. Seeing the severe, unconstitutional, and bigoted ongoing federal efforts to undermine existing hard-won protections under Section 504 of the Rehabilitation Act, California must once again lead the way.

Section 504 of the Rehabilitation Act, established in 1973, was a direct result of activism in California, where disability rights activists in San Francisco led the historic 504 Sit-in, demanding equal access and protection for people with disabilities. This incredible movement was a turning point in the fight for disability justice, and California's leadership in this fight remains a point of pride.

The recent federal complaint filed by Texas threatens to dismantle our precious healthcare and disability access protections. This is going to be the first of many deliberate efforts to erase basic human rights for people with disabilities, if not eliminate us completely.

Given California's legacy of advocating for the disabled, the state must continue to take deliberate and incisive action to protect the chronically ill and disabled community, including those suffering from conditions like ME/CFS and Long COVID. The federal government's planned strategy to eliminate our rights makes it even more critical for the California Board of Pharmacy to ensure that residents have expanded access to lifesaving compounded treatments. These therapies are essential for individuals who have no FDA-approved alternatives. Without them, many will continue to suffer. California must preserve its role as a leader in disability rights by making access to these therapies not just a priority but a guarantee for its most vulnerable residents.

The proposed sterile compounding regulations would place substantial financial burdens on pharmacies, effectively blocking access to essential treatments. At a time when federal protections are under attack, California cannot afford to restrict access to these life-saving therapies. Instead, the state must prioritize safeguarding healthcare access for its most vulnerable residents, ensuring that they receive the critical treatments they need to survive and thrive.

In contrast, the Board's failure to engage meaningfully with stakeholders and their refusal to amend the proposed regulations in response to the overwhelming public opposition—which includes over 11,000 petition signatures and hundreds of written and in-person comments—raises serious concerns about the adequacy of the Board's regulatory process. By stating that the public "does not understand federal or state laws," the Board continues to dismiss well-informed, thoughtful concerns from patients, healthcare professionals, and advocates who rely on these treatments. No meaningful collaboration has been demonstrated between the Board and healthcare providers, including doctors, pharmacists, and naturopaths, to ensure that patient needs are met and that the regulations support, rather than hinder, effective medical care.

I urge the Board to align these proposed regulations with the federal FDA and USP guidelines, which already provide a safe, well-established framework for compounding these essential medications. Further, I ask the Board to focus on creating a regulatory environment that makes these life-saving treatments more accessible and affordable, not less.

Thank you for your time and consideration. I trust that you will take immediate action to protect patient access to these critical compounded medications and ensure their continued availability at a cost that is both fair and sustainable.

Sincerely,

S. L. Johnson

Sara Johnson
Los Angeles, CA 90026

REFERENCES

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Martinez, Lori@DCA

From: Sonali Shah <studiosonali@yahoo.com>
Sent: Friday, February 14, 2025 10:18 AM
To: PharmacyRulemaking@DCA
Subject: Keep Category 1 Sterile Compounds Allowable

Hello California Board of Pharmacy,

I am urging you to please keep Category 1 steriles such as gluatatione, B12, NAD+, etc., **allowable** in the state. Being able to use this detoxification compounds has been life saving to me and my family and others that have genes that do not allow normal detoxification.

Thank you,
Sonali Shah

Martinez, Lori@DCA

From: Warren Freitag <wfreitag@pm.me>
Sent: Saturday, February 15, 2025 8:55 PM
To: PharmacyRulemaking@DCA
Subject: Public Comment on Title 16 CCR Sections 1735-1738

Dear California Board of Pharmacy,

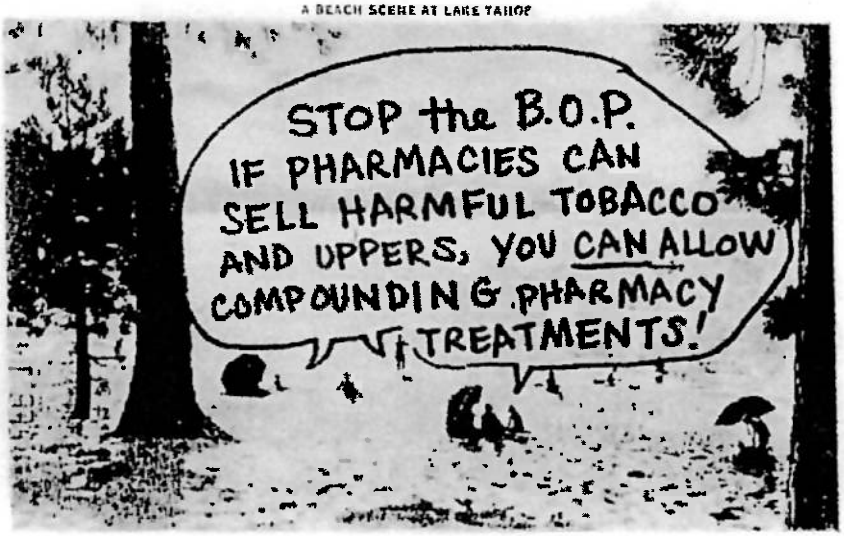
The restrictions you are proposing on natural compound treatments like Vitamin B12 and Glutathione is a slap in the face to our heroic firefighters and first responders. They selflessly expose themselves not just to physical harm but to the toxic chemicals that leech from devastating wildfires like the ones experienced in LA last month. Firefighters and first responders rely on these simple, affordable and effective compounds to detoxify so they can keep doing the critical work to keep all Californians safe. Another group at risk from these proposed regulations are those suffering from Lyme Disease and other ailments like Cystic Fibrosis, where the simple, affordable treatments have shown true efficacy. My good friend is one such person, and she relies on glutathione to treat her Lyme illness.

Another angle to consider here is that the banning of such compounds is a violation of the interstate commerce clause of the United States Constitution, and that any attempt to regulate the sale and distribution of these compounds can (and will) be challenged in federal court. Meanwhile, no other state is considering such a ban. All you are doing here is burdening the people of our great state with the requirement to cross state lines to seek these vital treatments.

Save yourselves the humiliation. Back down now.

Regards,
Warren
Concerned resident in Marin County

A BEACH SCENE AT LAKE TAHOE



POST CARD

HEY BOARD OF PHARMACY:
-WALGREENS still sells CIGARETTES.
-CVS still sells "uppers" CAFFEINE PILLS that send college kids to the ER.
FIREFIGHTERS have GIVEN Their LIVES AND ARE ASKING FOR YOU TO STOP TRYING TO BLOCK NEBULIZED GLUTATHIONE.

CHOOSE A REAL PROBLEM TO SOLVE!

FOUNDIMAGE.COM

P.S. MY BROTHER IS A FIREMAN! THEY TALK!!

BOARD OF PHARMACY
2720 GATEWAY OAKS DR.
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95833

736318 326981

CA 737

Crystal A. Frost, PhD
February 21, 2025

Public Comment on Proposed Amendments to Title 16 CCR Sections 1735-1738

Dear Members of the California State Board of Pharmacy,

I am writing this public comment on behalf of Stop the BOP, a nonpartisan patient-led movement advocating for the protection of access to sterile compounded medications that are essential to the lives of hundreds of thousands of Californians and utilized in countless medical communities across the nation and around the world.

The proposed amendments to Title 16 of the California Code of Regulations, Sections 1735-1738, impose unnecessary restrictions on access to Category 1 sterile compounds, such as glutathione, methylcobalamin, and NAD+. These regulations, as currently written, will devastate patient access to life-saving treatments in California, despite no evidence of safety risks warranting such measures.

In the wake of the Palisades and Eaton fires, Californians are grappling with the health consequences of prolonged toxic smoke inhalation, including toxin buildup in lung tissue. For many, the only effective treatment to address these toxins is nebulized and intravenous glutathione. These therapies are utilized by firefighters, Lyme Disease and Long COVID patients, and individuals with conditions like ME/CFS and methylation impairment. Denying access to these critical treatments endangers vulnerable populations and ignores the unique health challenges faced by our state.

FALSE CLAIMS MADE BY MEMBERS & EXECUTIVE STAFF

At the February 5 Board Meeting, certain senior board members and staff continued to misrepresent federal standards to the public and to other board members by:

1. Making false claims that USP Standards do not ensure sterile compounded medications are free of endotoxins.
2. Falsely blaming the FDA for the lack of access to glutathione in California and falsely claiming that glutathione is not available in 49 other states (which it is).

REFUTING FALSE CLAIMS

USP Standards Already Address Endotoxin Testing

On February 5, 2025, Member Maria Serpa asserted that the proposed updates to Title 16 are the only way to ensure Category 1 sterile compounds do not contain endotoxins. This is incorrect. Current USP standards already address and require measures to ensure sterile compounded medications meet endotoxin limits:

- **USP <797> (Sterile Compounding)**: Requires endotoxin testing for certain high-risk compounded sterile products (CSPs).
- **USP <85> (Bacterial Endotoxins Test)**: Establishes testing methods and specific endotoxin limits based on dosage form.
- **USP <71> (Sterility Testing)**: Verifies that CSPs are free of microbial contamination which are the usual cause of endotoxins.

The FDA Is Not to Blame for Glutathione's Inaccessibility in California

If the FDA were truly preventing the use of glutathione, glutathione would not be **readily available in 49 other states.*** Member Serpa claimed the FDA is responsible for glutathione's inaccessibility in California, but this is false. In fact, the FDA's interim policy places glutathione on its Category 1 list—meaning it is among the bulk drug substances FDA has not objected to during the list's development. As the FDA states:

> "Patients' care should not be disrupted while the [503A bulks] list is under development… FDA seeks to avoid unnecessary disruption to patient treatment while the Agency considers the bulk drug substances that were nominated with sufficient support to permit FDA to evaluate them."

Sterile compounded glutathione is not available in California for one reason only: *the underground enforcement actions of this very Board.*

StopTheBOP has contacted dozens of compounding pharmacies across the country and has not identified another state that prohibits Category 1 sterile compounds. Pharmacies offering Category 1 sterile products—such as methylcobalamin and glutathione—continue to provide them everywhere except California.

The Proposal Exceeds USP Standards in Three Major Ways

At the January 8 board meeting, Member Maria Serpa claimed these regulations do not exceed USP and FDA requirements, but *this is patently false*. The proposed regulations exceed USP Standards in the following ways:

- **USP does not require full stability studies for Category 1 or 2 sterile compounding.** These requirements only apply to Category 3 compounding. For the Board to mandate such studies—which can cost $10,000 to $30,000 per formulation—imposes an insurmountable financial burden on pharmacies. This will force them to limit offerings to the most generic formulations, eliminating the ability to create customized treatments based on individual prescriber orders.
- The **additional documentation of clinical circumstances** for APIs on the FDA's interim Category 1 list far exceeds FDA requirements. These APIs are already treated like any other active ingredient under FDA guidelines, with no such documentation mandate.
- The requirement to perform multiple tests on APIs, including **tests listed in USP Chapters above 1000** (informational-only chapters), is both excessive and unprecedented. California would be the only state enforcing such standards on 503As, further restricting access without improving safety.

I am deeply disturbed by the repeated false claims certain Board members and staff continue to make about federal standards. At best, these misrepresentations reflect negligence and incompetence, calling into question whether these proposed regulations are ready to be enacted. At worst, they suggest a deliberate effort to mislead both the public and fellow Board members—potentially serving hidden interests that seek to curtail patient access to safe, effective alternative medications. This troubling pattern raises serious concerns about the motivations behind these regulations and we hope other board members investigate these false statements as well and choose to act in the best interest of the public.

BROAD OPPOSITION AND SEVERE CONSEQUENCES

These burdensome regulations will have devastating consequences, especially for patients needing compounded treatments tailored to their specific health needs which is the entire purpose of 503A compounding pharmacies. While pharmacies may justify the cost of stability studies for a generic glutathione multiple-dose vial, they will not be able to produce more individualized options such as essential preservative-free

formulations or combinations. In essence, these regulations force 503A pharmacies to function as 503Bs which is effectively eliminating patient-specific sterile compounding.

Doctors, organizations, patients, and firefighters have repeatedly told you that they do not want these regulations. The Alliance for Pharmacy Compounding and numerous individual pharmacists have also voiced strong opposition. And yet, you continue to move forward, closing your ears to the outcry from those directly affected by your decisions.

As California faces an unprecedented public health crisis due to widespread toxic smoke exposure, including asbestos, lead, microplastics, and potentially thallium, this Board has a moral and ethical obligation to protect the public. Instead of actively making it harder for Californians to access critical treatments, preserve access by fixing this proposal.

Our asks are simple:

1. Align California's regulations with federal standards to ensure patients have access to essential Category 1 sterile compounded medications.
2. Adhere to USP by allowing Category 2 compounding without requiring full stability studies, provided sterility and endotoxin testing is performed and a reasonable beyond-use-date (e.g., 45 days refrigerated) is applied.
3. Eliminate adherence to USP Chapters above 1000, which are not enforceable requirements and are meant for informational purposes only.
4. Amend the language to specify that Title 16 sterile compounding regulations apply specifically to pharmacists and not to doctors.

The Board's mission should be to protect public health—not restrict access to therapies that enhance patient outcomes. I urge you to reconsider these proposed regulations and prioritize the well-being of Californians who depend on compounded medications for survival and quality of life.

Thank you for your attention and reconsideration.

Crystal A. Frost, PhD
Founder, Stop The BOP
email crystal@stopthebop.com
website stopthebop.com
phone +1 424 422 1807

From: Paul Narvaez
To: PharmacyRulemaking@DCA
Subject: Public Comment on Title 16 CCR Sections 1735-1738
Date: Friday, February 21, 2025 7:34:59 PM

Dear California Board of Pharmacy,

As a man who lives with his fiancee who suffers from Long Covid AND finds noticeable relief from injected glutathione, as well as NAD+ and other medications, I am writing to express strong opposition to the proposed regulations that would severely limit access to critical sterile compounded medications like injected and nebulized glutathione, methylcobalamin, NAD+, and others. These treatments are essential for many, including firefighters and chronic illness patients and the regulations would create unnecessary barriers that harm the healthcare system, businesses, and people of California.

During the February 5, 2025 meeting, certain board members misrepresented federal guidelines, claiming the FDA has recommended glutathione be restricted. However, glutathione remains on the FDA's Category 1 bulk compounds list, and is therefore legal under their current policy. USP guidelines also do not mandate stability testing for these compounds. Despite this, your proposal introduces extreme testing requirements that far exceed federal standards without any adequate safety-based justification.

The unfeasible financial burden these regulations would place on pharmacies is a critical concern. Member Serpa's cost estimates—$16.10 per glutathione vial and $8.06 per methylcobalamin vial—dramatically understated the actual costs of stability testing. These tests actually range from $10,000 to $30,000 per API. These prohibitively expensive tests would force pharmacies to discontinue offering most if not all formulations of these treatments, eliminating access to life-saving medications.

The need for treatments like nebulized glutathione is more urgent than ever since southern California's severe Urban-Wildfires released record levels of harmful toxins like lead and asbestos into the environment. Nebulized glutathione has demonstrated efficacy to reduce these harmful substances in the body. Restricting access to these treatments would escalate health risks, including fatal cancers, for first responders, vulnerable residents, and future generations.

I appreciate comments made by Members Chandler, Hughes, and Thibeau, who expressed desire to protect patient access. Member Hughes emphasized the importance of these treatments, not just for firefighters but for people with ME/CFS, Long COVID, and other disabilities. He stated, "There are hundreds, if not thousands, of people using these compounded medications across the state," and called for California to lead the way in research that improves access.

The public opposition to these regulations is overwhelming, with over 11,000 signatures on a

petition—with an estimated 1,000+ from California firefighters—and hundreds of pages of comments submitted in writing and in person over the past year. Yet, the Board has failed to meaningfully respond to meaningful input from dozens of medical experts, consistently ignoring their expertise. The Board has repeatedly suggested that the public doesn't understand federal and state laws or their application, dismissing the well-informed concerns raised by patients, healthcare professionals, and advocates. The failure to engage meaningfully with stakeholders undermines the credibility of the Board's engagement process and has raised serious concerns about regulatory overreach.

As written, the proposal creates unnecessary barriers that will severely limit access to life-saving treatments. These barriers create an unjustifiable financial burden on patients and pharmacies and fail to reflect the true costs and needs of the community. I strongly urge The Board of Pharmacy to either (a) withdraw the proposal entirely from consideration, or (b) send these proposed regulations back to committee and re-write them to align them with and not exceed federal and Pharmacopeia standards by making the following changes:

* Adhere to USP by allowing Category 2 compounding without requiring full stability studies, provided sterility and endotoxin testing is performed and a reasonable beyond-use-date (e.g., 45 days refrigerated) is applied.
* Eliminate adherence to USP Chapters above 1000, which are not enforceable requirements and are meant for informational purposes only.
* Amend the language to specify that Title 16 compounding regulations apply only to pharmacists. As written, this board appears to begin regulating medical practices which is regulatory overreach.
* Remove the requirement of additional documentation of "clinical circumstances" which is not required by the FDA.

Thank you for your time and attention to this urgent matter. I trust you will act in the best interest of public health and patient access.

Sincerely,

Paul Narvaez
(213) 840-1375

From: elle seibert
To: PharmacyRulemaking@DCA
Cc: Damoth, Debbie@DCA
Subject: Written Comment in Opposition to Proposed Regulations in Title 16
Date: Friday, February 21, 2025 9:30:00 PM

Dear President Oh and Board of Pharmacy Members:

For the last time, I am writing to express my grave concerns regarding the regulatory changes proposed in Title 16 CCR Sections 1735-1738. Throughout the rulemaking process, these regulations have faced near unanimous opposition from patients, healthcare professionals and other stakeholders. It has become increasingly clear that there is a stark difference between intentionality and outcome with respect to the Board's actions to date.

To each board member, I urge you, please, to listen, and to consider the real life implications of each and every one of your votes.

I am writing to you as just one person, disabled by Long COVID, fighting for continued survival in a city that has just faced a historic natural disaster.

As you know, the wildfires in Los Angeles have been unprecedented for the State of California - upwards of 56,000 acres have burned, including homes, cars and industrial spaces. In addition to the direct damages caused by the fires, Angelenos continue to reckon with the health implications of poor air quality. While we are grateful that the fires have been contained, *we are only just at the beginning.*

As we know from 9/11, continuing to live, work and play in close proximity to cleanup efforts has devastating long term effects on health with many survivors being diagnosed with short latency cancers due to poor air quality. It is a known fact that more people died from health complications relating to the air quality post-9/11 than on the day of the attacks. What is less known is that there are over 113,000 people registered on the World Trade Center Registry for longitudinal research into the long term health effects of exposure to 9/11 air. This cohort is not purely comprised of first responders - it includes ordinary people of all ages who just happened to live in proximity to the attacks taking place on 9/11.

According to the Coalition for Clean Air webinars on General Safety Practices during this time, the clean up efforts will take 6-8 months *at the very least.* As efforts to move and safely store an unprecedented volume of ash takes place, hazardous air pollutants and carcinogens are being released into the air we breathe. Despite this, there is a tragic dearth of information on risk and mitigation being provided by the current administration - many Angelenos are not

aware of the risks we take on by resuming "life as usual" just because the fires no longer burn.

Unlike in 9/11, we have the tools - but the past actions of the Board have put those tools at risk. Thanks to the groundbreaking research taking place at Volunteer Fire Foundation, we *know* that nebulized glutathione reduces levels of high range environmental toxins, mycotoxins and PFAS ("forever chemicals") in first responders. Thanks to the work of 9/11 activists like Lila Nordstrom, we *know* that people of all ages -- including children -- living in close proximity to clean up sites are at risk of developing serious long term health complications due to worsening air quality related to the transportation and storage of ash from burn sites.

I said it at last month's board meeting and I will say it again: *Angelenos deserve access to nebulized glutathione too. We deserve to survive and thrive in the midst of natural disaster. We deserve to survive and thrive in the midst of a pandemic. We deserve to survive and thrive, period. But access to critical therapies like nebulized glutathione is at risk during a time when we need them the most.*

The vote taking place in March presents an opportunity, not only to learn from the events of 9/11, but to do better. So, do better. Listen to your stakeholders. Send these regulations back to committee. Align with USP standards. Re-build these regulations from the ground up in partnership with the people most affected. Center the needs of the most marginalized.

Thank you,

Elle Seibert
Founder, The Pidgin Co-Op
Organizer, Got Long COVID?
Consultant, NIH RECOVER
(e): elle@thepidgincoop.com