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1	1737.1	B. Go	The response by the Board that both proposed as well as existing regulations on compounding, as currently worded, do not infringe on the practice of compounding by non-pharmacist licensees under the jurisdiction of other California professional boards, is not satisfactory for the following reasons: 1. You responded with comments from only one board, the Medical Board of California, which only regulates MD's. This does not apply to other licensees such as DO's, nurses, ND's, dentists, and veterinarians, who may also have the right to compound medications in-office without a pharmacist and without interference by the Board of Pharmacy. Furthermore, even the MD's right to compound is still in jeopardy based on current wording of the Board's regulations, for the following reasons: a. The Medical Board's letter noted that only the Medical Board has the right to discipline its licensees. This would only apply if the licensee was being disciplined as an MD, not if they were being disciplined as a person practicing pharmacy without a license. Again as previously stated, the Board of Pharmacy's jurisdiction is to regulate the practice of pharmacy, and therefore practicing pharmacy without a license would fall within their purview. Both currently existing 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:	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the comment does not address modifications made in the third modified text. The Board has previously considered this and similar comments and provided responses throughout the rulemaking, including for example the response provided in row 5 available here, which included in part," Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment. Board staff note that the Board previously considered this comment, most recently during the January 8, 2025, Board Meeting and determined that the requested change is not appropriate. As was previously shared, staff note the Board only has jurisdiction over individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a physician. Business and Professions Code section 4170(c) makes clear that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2 of the Business and Profession Code) with respect to its licensees." The Board refers the commenter to Business and Professions Code section 4170 as well as the Board's jurisdiction. The Board also recommends that the commenter review the Board's Initial Statement of Reason that describes the Board's jurisdiction to gain a better understanding of the applicability of the Board's regulations. The commenter also appears to be provided comments about a statutory proposal related to the regulation if IV hydration clinics. Staff refer the commenter to the Board's proposed statutory proposal for an understanding of the Board's legislative proposal. Staff note that the language in the statutory proposal does include explicit language that it would not apply to a facility for which a professional director is on site while sterile compounding occurs.

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			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	

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			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.'	
2	1737.5	K. Scott Guess	Please validate the augmentation above USP 800 to certify C-PEC's every 6 months over the annual certification codified in USP 800.	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the comment does not address modifications made in the third modified text. Board staff further note that the commenter may be confusing requirements as USP 800 Chapter does not include certification requirements, rather is builds upon Chapters 795 and 797. The certification requirements established in USP 797 (Section 5), establishes the requirement for biannual certification for sterile compounding. The certification requirements established in USP 795 (Section 6.1) establishes the requirement for certification at least every 12 months for nonsterile compounding.
3	1737.6	K. Scott Guess	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.	Board staff have reviewed the comment and do not recommend a change to the proposed recommended text. The Board's proposed regulation text requires the facility to evaluate whether the use of wipe sampling in their respective facility is appropriate. Staff note that wipe sampling may not be appropriate in all facilities, but at a minimum, consideration of the use of wipe sampling must be performed and documented.
4	1737.7(a)	M. Cottman	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	Board staff have reviewed the comment and believe that a change to the regulation text is appropriate after consideration of this and other comments received related to this provision. It is important to note that numerous sources have been cited by the Board demonstrating risks of cross contamination and contamination of gloves. Additional information from OSHA provides further examples of manipulations that can cause escape of HD residue by splattering, spraying, and aerosolization include:

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			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!	• piercing drug vial septa with needles or dispensing pins; • withdrawal of needles or pins from drug vials; • drug transfer using syringes and needles or dispensing pins; • breaking open of ampules; • drug transfer from ampules using filtered needles or filter straws; • expulsion of air from a drug-filled syringe; • piercing injection ports of IV bags or bottles with needles to inject HDs; • spiking delivery ports of HD-containing IV bags or bottles with the sharp spike of IV administration sets; and • removing air from the IV administration sets by running HD containing fluid through the set (i.e., priming the line). Staff offer the following recommended change to section 1737.7 directly from the USP 800 Chapter. (~~e~~**a**) Outer gloves used for HD compounding shall be ***carefully removed and discarded immediately into a waste container approved for trace contaminated waste inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC as established in USP 800 Section 7.6*** ~~***changed between each different HD preparation, unless preparing multiple HD preparations of the same drug or preparing multiple HD preparations for a single patient.***~~
5	1737.7(c)	Kaiser	In attempting to impose the requirement that compounding personnel change their outer HD gloves after each different HD 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	Board staff have reviewed the comment and believe that a change to the regulation text is appropriate after consideration of this and other comments received related to this provision.

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			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." 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 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	It is important to note that numerous sources have been cited by the Board demonstrating risks of cross contamination and contamination of gloves. Additional information from OSHA provides further examples of manipulations that can cause escape of HD residue by splattering, spraying, and aerosolization include: • piercing drug vial septa with needles or dispensing pins; • withdrawal of needles or pins from drug vials; • drug transfer using syringes and needles or dispensing pins; • breaking open of ampules; • drug transfer from ampules using filtered needles or filter straws; • expulsion of air from a drug-filled syringe; • piercing injection ports of IV bags or bottles with needles to inject HDs; • spiking delivery ports of HD-containing IV bags or bottles with the sharp spike of IV administration sets; and • removing air from the IV administration sets by running HD containing fluid through the set (i.e., priming the line). Staff offer the following recommended change to section 1737.7 directly from the USP 800 Chapter. (~~c~~a) Outer gloves used for HD compounding shall be ***carefully removed and discarded immediately into a waste container approved for trace contaminated waste inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC as established in USP 800 Section 7.6*** ~~***changed between each different HD preparation, unless preparing multiple HD preparations of the same drug or preparing multiple HD preparations for a single patient***~~.

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			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 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	

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			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 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.	

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			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.	
6	1737.7(c)	CSHP	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.	As was previously noted in prior responses to these comments, the practice of changing gloves as proposed in the regulation text is currently in practice in numerous facilities as a means to prevent cross contamination. Incorporating best practices implemented by hospitals and other facilities into the Board's regulation is appropriate and necessary to reduce patient harm and inappropriate exposure to hazardous drugs. Below is an example of an excerpt from the facility's SOP submitted to the Board in December 2024, "Outer gloves used for compounding must be changed between each different HD drug." Below is another example from SOPs submitted to the Board in January 2025 from a health system, "Outer gloves used for compounding must be changed between each different HD drug." Board staff have reviewed the comment and believe that a change to the regulation text is appropriate after consideration of this and other comments received related to this provision.

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			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	It is important to note that numerous sources have been cited by the Board demonstrating risks of cross contamination and contamination of gloves. Additional information from OSHA provides further examples of manipulations that can cause escape of HD residue by splattering, spraying, and aerosolization include: • piercing drug vial septa with needles or dispensing pins; • withdrawal of needles or pins from drug vials; • drug transfer using syringes and needles or dispensing pins; • breaking open of ampules; • drug transfer from ampules using filtered needles or filter straws; • expulsion of air from a drug-filled syringe; • piercing injection ports of IV bags or bottles with needles to inject HDs; • spiking delivery ports of HD-containing IV bags or bottles with the sharp spike of IV administration sets; and • removing air from the IV administration sets by running HD containing fluid through the set (i.e., priming the line). Staff offer the following recommended change to section 1737.7 directly from the USP 800 Chapter. (~~c~~**g**) Outer gloves used for HD compounding shall be ***carefully removed and discarded immediately into a waste container approved for trace contaminated waste inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC as established in USP 800 Section 7.6*** ~~***changed between each different HD preparation, unless preparing multiple HD preparations of the same drug or preparing multiple HD preparations for a single patient.***~~

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			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	

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			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	

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			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.	
7	1737.15(a)	Kaiser	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.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Board staff note that the recommendation to add in a provisions for the study to be "peered reviewed" does not ensure an independent reviewer is involved.
8	1737.16	K. Scott Guess	Spill control is already addressed in USP 800. It is unnecessary for the Board to restate the need for spill control SOP.	Board staff note that the recommended to add in a provisions for the study to be "peered reviewed" does not ensure an independent reviewer was part of the process. Further, staff note that the proposed regulation ensures that the facility's SOPs makes certain that a qualified person is available at all times.