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1	1737	Marie Cottman	General statement of: In addition to the standards in the USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed. Vs. In addition to the standards in the USP Chapter 800, the following requirements apply to the compounding of HDs or performing crushing or splitting tablets or opening capsules of antineoplastic HDs. 1) This statement is used inconsistently throughout the proposed rules for hazardous compounding. **Recommend you create a consistent statement that can be used at the beginning of each numbered rulemaking. Delete redundant and repetitive phrasing.** 2) The expanded statement about crushing or splitting tablets is not included, but seems appropriate for sections 1737.2, 1737.7 PPE, 1737.8 Hazard Communications, 1737.12 Dispensing final dosage form, 1737.15 Deactivating, Decontamination, Cleaning and Disinfecting, 1737.16 Spill Control	Board staff note that nonsubstantive changes may be made in the proposed regulation text consistent with the Board's action where necessary. The commenter does not appear to be recommending substantive changes to the proposed regulation text in section 1737, rather appears to be recommending the Board review text for consistent use of language. Provided below is an example of a nonsubstantive change to standardize text. **1737. Handling of Hazardous Drugs.** **In addition to the requirements in United States Pharmacopeia (USP) General Chapter 800 (USP Chapter 800), *Hazardous Drugs – Handling in Healthcare Setting*, ~~This~~ this** article applies to the ~~handling~~ compounding of Hazardous Drugs (HDs) or **~~performing "other manipulations" included in Table 1 of the Chapter~~ crushing or splitting tablets or opening capsules** of antineoplastic HDs, ~~of Hazardous drugs~~ **~~established by United States Pharmacopeia (USP) General Chapter 800 (USP~~**

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				~~Chapter 800), titled *Hazardous Drugs – Handling in Healthcare Setting*. In addition to the standards in the USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article.~~
2	1737.1	CA Rheumatology Alliance And CA Society of Plastic Surgery	We have reviewed the staff responses to our comments and continue to be concerned with the applicability of the proposed regulations on physicians and their ability to "compound" medications in their offices. Although physicians may not be under the enforcement jurisdiction of the Board of Pharmacy, we believe the proposed regulations would change the standard of care for when physicians compound medications and will not allow rheumatologists/physicians to buffer injection/ infusion medications in-office. We are interpreting the proposed regulations to require a pharmacist be present or performing the buffering of the injection/ infusion medications. Rheumatology practices/physicians would not be able to afford to employ a pharmacist for this one purpose. This would lead to rheumatology practices no longer offering this service for our patients. Patients would then be forced to obtain their injection/infusions at a hospital or infusion center which would not only be less convenient for our patients, but it would be more expensive for the patient and the overall healthcare system. We believe it is important to note we are not aware of any issues with rheumatologists/physicians "compounding" injection/ infusion medications. We would like to propose the Board of Pharmacy adopt the language suggested by the California Medical Association as shown below: **§ 1737.1:** In addition to the requirements in USP Chapter 800 and Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) the following requirements apply to the compounding of Hazardous Drugs. **This article shall not apply to compounding by or under the direct supervision of a licensed physician and surgeon.**	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 has 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.

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				It may be appropriate for the commenter to confer with their licensing board to discuss their concerns. Board staff note that the Medical Board of California has previously provided a written response to individuals inquiring about the applicability of the Board of Pharmacy's regulations to individuals and practices that operate under the jurisdiction of the Medical Board of California. Below is the information provided from the Medical Board - - Dear Ms. Sodergren: I understand that some concerns have been raised by stakeholders about the applicability of the Board of Pharmacy's pending compounding regulations to licensees of the Medical Board of California (MBC). Existing statute (see Business and Professions Code (BPC) section 2220.5) makes it clear that only the MBC can discipline its physician licensees. Whenever a physician is engaging in compounding (or any other action that their medical license authorizes them to perform) they must always do so consistent with the standard of care. For the purposes of MBC's enforcement program, the standard of care is established by expert testimony in the context of

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				the facts and circumstances of a specific case. It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding, especially since some of the proposed regulations reflect what is already required for physician compounding under federal law, including, but not limited to, Section 503A of the Federal Food, Drug, and Cosmetic Act (BPC section 2225(b) allows MBC to investigate violations of federal law related to the practice of medicine). Feel free to share this message with others as you see fit who might also be concerned about the applicability of their pending regulations to the physician community. Please contact me if you have any further questions. Sincerely, Reji Varghese Reji Varghese is the Executive Director for the Medical Board of California. The Medical Board is charged with evaluating compounding practices and the standard of care relevant to its licensees.
3	1737.1(a)	Marie Cottman	1707.2(e) allows an out for when the patient or the patient's agent refuses consultation.	Board staff have reviewed the comment and do not

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			By having this special consultation for HDs in section 1737.1(a), it becomes a SHALL ***always***, even when the patient doesn't want it. This rule would be much better added to 1707.2 as an additional requirement. As a licensee, it is always frustrating to have to identify multiple sections that address the same requirements! **Recommend to remove and add rulemaking to add this language to 1707.2.**	recommend a change to the proposed text. Board staff note that, consistent with the provisions in 1707.2, a pharmacist is required to initiate a consultation; however, a patient may decline the consultation with the pharmacist.
4	1737.2	Marie Cottman	The expanded statement about crushing or splitting tablets is not included, but seems appropriate for sections 1737.2	Board staff have reviewed the comment and do not recommend a change in the proposed text. Staff note that the Board's regulation text establish minimum standards and that specifically for the list of hazardous drugs, inclusion of "crushing or splitting tablets" is not necessary.
5	1737.5(c)	UCSD Health	One written comment response I would like to address is on 1737.5(c) that prohibits a pass through between a classified space and unclassified space. The board response is title 24, section 122 prohibits passthrough between classified and unclassified spaces in HD environment. • This was an update to title 24 in 2022. The problem with putting building codes into pharmacy law is building codes apply at the time of permitting so if I applied for permits in 2018 those permits would apply not 2022. In fact, the change in 2022 was the result of a misreading of USP 800 by the California Building Standards Commission where USP says no pass-through refrigerator and not pass throughs. This has actually been corrected in the latest Title 24 version 2024 now is amended. The code now says: o *Section 1224.19 "This section to align with USP which allows a passthrough from the buffer room to unclassified area but not the refrigerator".* a. **Recommendation**: Revise language to be consistent with USP 800 or FDA language. I would ask the board align with USP 800 similar to the California Building Standards Commission and the FDA and allow for a pass	Board staff have reviewed the comment and have also confirmed that the California Building Standards Commission is considering a change to the building code during its February 2025 meeting. Although the outcome of this meeting is not yet known, given that the change is being considered, it appears appropriate to remove what was section 1737.5(c). Board staff believe the following change is appropriate. 1737.5 (c) ~~Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking.~~

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			through between hazardous classified and unclassified space. The	**~~Effective [OAL insert six months following the effective date]~~** ~~A~~ **~~a pass-through is not allowed between the hazardous drug buffer room~~** ~~C-SEC~~ **~~into an unclassified space~~**.
6	1737.5(c)	Kaiser Perm And CSHP	Commenter requests that the section be stricken from the language. The California Building Standards Commission has proposed deleting the prohibition of a pass-through between a hazardous drug buffer room and an unclassified area in its 2024 Triennial Code Adoption Cycle, which will become effective on January 1, 2026. The Building Standards Commission's recommendation is copied below for reference (***emphasis*** added): **1224.19.3.3.2.8 Pass-throughs.** HCAI proposes an amendment to remove the prohibition of a pass-through between the hazardous drug buffer room and any unclassified area and to add a restriction for refrigerator pass-through. The proposed amendment is to align with United States Pharmacopeia General Chapter, USP-GC Hazardous Drugs-Handling in Healthcare Settings (USP-GC). ***The USP-GC standards allow a passthrough from the buffer room to unclassified areas but not the refrigerator***. This revision will align with USP-GC. It will not cause financial burden to the facilities. When the new building code goes into effect on January 1, 2026, only compounding suites that were permitted between January 1, 2020 and December 31, 2025 cannot have a pass-through between the HD buffer room and unclassified areas. If the Board chooses to adopt this restriction in its regulations, it will be cherry-picking a standard that is not included in current building code (as of 1/1/2026) and is not supported by the USP chapters. If the Building Standards Commission's recommendation alone is not persuasive, then logically evaluating the most significant source of microbial contamination should be. The personnel entering the sterile compounding suite present the greatest risk for microbial	Board staff have reviewed the comment and have also confirmed that the California Building Standards Commission is considering a change to the building code during its February 2026 meeting. Although the outcome of this meeting is not yet known, given that the change is being considered, it appears appropriate to remove what was section 1737.5(c). Board staff believe the following change is appropriate. 1737.5 ~~(c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking.~~ **~~Effective [OAL insert six months following the effective date]~~** ~~A~~ **~~a pass-through is not allowed between the hazardous drug buffer room~~** ~~C-SEC~~ **~~into an unclassified space~~**.

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			contamination in the cleanroom. A pass-through reduces human traffic in and out of the buffer room thus reducing opportunities for microbial contamination in the sterile compounding suite.	
7	1737.6	Marie Cottman	If 1737.6 does not require the use of environmental wipe sampling, what is the point of writing ANOTHER SOP? Documentation of consideration should be sufficient. **Recommend to reword:** The premises shall consider environmental wipe sampling and if implemented, SOPs of a premises where HDs are handled shall address describe provisions for environmental wipe sampling for HD surface residue, its frequency, and areas of testing, levels of measurable contamination, and actions when those levels are exceeded. Nothing in this section is intended to require the use of environmental wipe sampling.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that documentation within the SOP shall memorialize the facility's consideration of the use of environmental wipe sampling along with the provisions for use when determined appropriate. Staff believe clarification of the text may be appropriate to make clear the requirement. Staff offer the following: 1737.6 In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed. ~~Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article.~~ The **premises shall consider environmental wipe sampling, and** SOPs **~~of a premises~~** ~~where HDs are handled~~ shall **~~address~~ describe the consideration of and provisions for** environmental wipe sampling for HD surface residue**~~, its frequency, and~~**

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				~~**areas of testing**, levels of measurable contamination, and actions when those levels are exceeded~~. **Nothing in this section is intended to require the use of environmental wipe sampling.**
8	1737.7	Marie Cottman	The expanded statement about crushing or splitting tablets is not included, but seems appropriate for sections 1737.7	Board staff have reviewed the comment and do not recommend a change in the proposed text. Staff note that the Board's regulation text establish minimum standards and that specific provisions for PPE in the Board's proposed regulations do not need to extend to "crushing or splitting tablets"
9	1737.7(b)	Marie Cottman	In section A, the phrase "chemotherapy gloves that meets the ASTM D-6978 standard" is also used. But at the end of this provision, there is a sneaky distinction that the gloves be "labeled to meet ASTM D-6978." NOT ALL ASTM compliant gloves are ***labeled*** as such. The ASTM designation is a 'pay to play' label and many gloves meet the standard as is indicated in their COA, but do *not* pay to have the ASTM label. Further, USP 800 section 7 already requires "/…two pairs of chemotherapy gloves are required for compounding sterile and nonsterile HDs." **Recommend to revise by removing "labeled to meet the ASTM standard".** (b) The outer pair of chemotherapy gloves that meets the ASTM D-6978 standard shall be changed as recommended by the manufacturer's documentation. Documentation from the manufacturer shall be readily retrievable. For sterile HD compounding, both pairs of gloves ~~labeled to meet the ASTM D-6978 standard~~ shall be sterile.	Board staff have reviewed the comment and appreciate the commenter highlighting their concern. After reviewing the comment, staff believe that the language in the proposed regulation text is generally covered in the Chapter and note that some of the activities described fall under the purview of CalOSHA. The proposed text established in subdivision (a) & (b) do not appear to create patient safety issues, but are more directed at personnel safety. Although the commenter is specifically referring to subdivision (b), staff believe removing

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				subdivisions (a) and (b) are appropriate as a result. 1737 (a) **~~Two pairs of chemotherapy gloves that meet the ASTM D-6978 standard shall be worn for handling HD waste, cleaning HD spills, and performing routine cleaning in HD areas.~~** (b) **~~The outer pair of chemotherapy gloves that meets the ASTM D-6978 standard chemotherapy gloves shall be changed~~** ~~every 30 minutes during HD compounding unless otherwise~~ **~~as recommended by the manufacturer's documentation. Documentation from the manufacturer shall be readily retrievable. For sterile HD compounding, both pairs of gloves labeled to meet the ASTM D-6978 standard shall be sterile.~~**
10	1737.7(c)	Marie Cottman	As was presented to the board previously, this is an expensive and unnecessary rule. Either the compounder can prepare sterile preparations without cross contamination, or they cannot, and gloves should be changed for every different preparation (HD or NOT)! Sterile gloves are costing $1.50 to $3.85 / pair. In addition to the expense, the change in process for all sterile compounders might	Staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff note that information released by USP explicitly state, "Consider all PPE

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			result in a shortage of gloves because the use will not double, but it might increase by 10 or 20 fold! IF you cannot provide evidence of the NEED to change the gloves more often than required by the manufacturer, then **Recommend to remove.**	worn when handling HDs to be contaminated with, at minimum, trace quantities of HDs…" The Chapter in section 3 provides examples of potential opportunities of exposures based on activity, including compounding. If gloves are contaminated, it can result in cross contamination of preparations for patients. Staff note that the proposed second modified text provides flexibilities to allow for multiple HD preparations of the same drug or when preparing HDs for a single patient where the risk of cross contamination is not present. Staff note that costs may vary depending on the types of HD gloves, e.g. sterile versus nonsterile, and vendors used, etc. The Chapter determines the types of gloves that must be used depending on the functions being performed and establish a number of requirements for changing gloves. The Board's proposed regulations are addressing the potential for cross-contamination. As established in USP and in the conclusions of published research, Hazardous Drugs Contamination of Drug Preparation Devices and Staff: A Contamination Studies

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				Simulating the use of Chemotherapy Drugs in a Clinical Setting[1], "In 4 of the 5 CSTD systems, residue from HD-contaminated vials spread as the vial was handled in a pharmacy environment. HD contamination transferred initially to pharmacy PPE, then spread to ancillary products such as IV bags, IV sets, and transport bags, which, in turn contaminated nursing PPE…" As this study demonstrates, cross-contamination can occur even with the use of CSTDs.
11	1737.7(c)	Stanford Health	**Comment:** While we acknowledge that Closed System Transfer Devices (CSTDs) do not completely eliminate contamination risks, they are specifically designed to prevent the escape of hazardous drugs or vapors outside the system. Most hazardous drug compounding in hospital practice involves the use of closed system drug vials, which, when paired with CSTDs, further reduces the potential for contamination. Taken together, implementing a requirement for excessive glove changes, in addition to the use of CSTDs with closed-system vials, offers negligible added safety benefits to patients. The proposed requirement introduces operational burden and significant costs incurred for HD gloves and HD waste disposal. **Recommendation:** Remove language to be consistent with USP 800 or revise language to require changing outer HD gloves, between each	Board staff have reviewed the comment and do not recommend a change to the proposed text. As the studies provided reveal, the use of a CSTD may reduce the risk of contamination but does not eliminate the risk. The Board appreciates the use of the technology as an important safety measure and notes the following from USP. As included in previous response to comments, USP Commentary provides, "CSTD provides adjunct control during compounding; however, additional controls are needed to prevent HD contamination, especially during the movement of ingredients and materials into and out of the C-PEC."

[1] Evan Call, Brian Bill, Chad McLean, Nathan Call, Allyn Bernkopf, Craig Oberg. (2017) Hazardous Drug Contamination of Drug Preparation Devices and Staff: A Contamination Study Simulating the Use of Chemotherapy Drugs in a Clinical Setting, *Hospital Pharmacy*, 52(8): 551-558, https://pubmed.ncbi.nlm.nih.gov/

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			different HD preparation, if compounding is performed without a CSTD.	Further, in the conclusions of published research, Hazardous Drugs Contamination of Drug Preparation Devices and Staff: A Contamination Studies Simulating the use of Chemotherapy Drugs in a Clinical Setting[2], "In 4 of the 5 CSTD systems, residue from HD-contaminated vials spread as the vial was handled in a pharmacy environment. HD contamination transferred initially to pharmacy PPE, then spread to ancillary products such as IV bags, IV sets, and transport bags, which, in turn contaminated nursing PPE…" As this study demonstrates, cross-contamination can occur even with the use of CSTDs. This study also supports the USP Commentary statements related to this area that were previously noted in staff recommended responses. Photos included in Figure 1 clearly show the contamination of gloves.
12	1737.7(c)	Kaiser Perm	Commenter recommends that this section should be stricken. Anything short of deleting this section of regulation is inadequate. There is no evidence to support the notion that requiring compounders to change their outer HD gloves more frequently than the USP 800 recommended frequency of every 30 minutes will prevent contamination with HD residues. Commenter previously	Board staff have reviewed the comments and do not recommend any changes to the proposed text. (Note that the language referenced is now section 1737.7(a) because of the

[2] Evan Call, Brian Bill, Chad McLean, Nathan Call, Allyn Bernkopf, Craig Oberg. (2017) Hazardous Drug Contamination of Drug Preparation Devices and Staff: A Contamination Study Simulating the Use of Chemotherapy Drugs in a Clinical Setting, *Hospital Pharmacy*, 52(8): 551-558, https://pubmed.ncbi.nlm.nih.gov/

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			outlined several negative second-order effects that this change will precipitate. Commenter states that the Board has never weighed the purely speculative benefits of more frequent outer HD glove changes against the real negative outcomes that the regulation will cause. Correctly donning sterile gloves is critically important to safe compounding and is a significant risk point for introducing microbial contamination into the sterile compounding environment; consequently, facilities are required to perform initial gloved fingertip sampling "to ensure that personnel… put on sterile gloves without contaminating them." Because each glove change carries some risk of microbial contamination, basic probability dictates that mandating that compounders change the outer HD glove more frequently increases the overall risk of contamination. For example, the two equations below give the respective probabilities of microbial contamination for two scenarios. The first equation, p1, is the imagined probability of contamination for an individual who performs ten glove changes in a shift with the probability of contamination during any one glove change of 0.2%. The second equation, p2, is the imagined probability of contamination for the same individual who now performs fourteen glove changes in a shift (an increased frequency of glove changes based on the Board's proposed regulation) with the probability of contamination during any one glove change of 0.2%. The estimated probability of contamination for glove changes of 0.2% is a conservative estimate based on a study in the peer-reviewed literature that found a contamination rate of 0.34% for glove changes in a pharmacy sterile compounding suite when sterile gloves were used. As demonstrated by equations below, the risk of microbial contamination during this fictitious employee's shift will markedly increase with more frequent glove changes: $p1=1-(0.998)10=1.98\%$ $p2=1-(0.998)14=2.76\%$ Commenter states that the Board has also materially failed to meet the basic minimum procedural requirements of the California Procedure Act (APA). First, while the law allows a regulator to "aggregate and summarize repetitive… comments as a group… and… respond to repetitive comments… as a group," as described in *Sims v. Department of Corrections & Rehabilitation*, the regulator is still required to respond to each comment. In our comment letter dated	proposed deletion of subsections (a) and (b).) Staff note that the intent of the Chapter in part is to protect patients from harm associated with exposure to hazardous drugs. USP was developed to provide guidance on protecting any individual who may have exposure to HDs. As the Chapter establishes, gloves must be changed if contaminated. This is a requirement of the Chapter. The Chapter further provides in Section 7.6, "Consider all PPE worn when handling HDs to be contaminated with, at a minimum, trace quantities of HDs." The use of a CSTD may reduce the risk of contamination but does not eliminate the risk. The Board appreciates the use of the technology as an important safety measure and notes the following from USP. As included in previous response to comments, USP Commentary provides, "CSTD provide adjunct control during compounding; however, additional controls are needed to prevent HD contamination, especially during the movement of ingredients and materials into and out of the C-PEC."

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			December 6, 2024, we highlighted three areas of concern with the proposed regulation: (1) the lack of evidence to support the proposed regulation, (2) the significant cost that the proposed regulation will impose on California businesses, and (3) the likely negative environmental impacts of the proposed regulation. In the Board staff's response to public comments, Kaiser Permanente's comments were aggregated with several other commenters. The Board staff's response to the aggregated comments addressed the reasons why the Board does not believe that the use of a CSTD would obviate the need to the proposed requirement; however, there was no response to the three areas of concern outlined in Kaiser Permanente's December comment letter. Therefore, the Board likely failed in its obligation to respond to each public comment received. As outlined in *Western States Petroleum Association* v. *Board of Equalization*, under the APA, regulators are required to "provide in the [rulemaking] record facts, evidence, documents, testimony, or other evidence upon which the agency relies to support its initial determination [of economic impact]." Moreover, the regulator must demonstrate "that there was some factual basis for [its] determination," and this requirement is not met "by an opaque calculation unsupported by any facts or other evidence explaining its validity as a reasonable estimate." In our December 6, 2024 comment letter, we attempted to correct a significant error in the Board's estimate of the cost of a pair of sterile gloves used for HD compounding. In the Modified Initial Statement of Reasons, the Board states, "an online search reveals that the cost of a pair of gloves is about $.14 [per] pair." In our comments, we indicated that one pair of sterile, ASTM D6978 gloves (the gloves required for sterile HD compounding) cost between $1 and $4 per pair. The Board's erroneous estimate of the cost of sterile HD gloves likely contributed to its finding in the Modified Initial Statement of Reasons that there will be "minimal ongoing costs" associated with the proposed regulations including "up to $150,000 over a ten-year period for administrative and maintenance workload and Suppl[y] [costs]" and the overall determination "the proposed regulations will not have a significant statewide adverse economic impact…". Therefore, the Board likely	The Board's proposed regulations are addressing the potential for cross-contamination. As established in USP and in the conclusions of published research, Hazardous Drugs Contamination of Drug Preparation Devices and Staff: A Contamination Studies Simulating the use of Chemotherapy Drugs in a Clinical Setting[3], "In 4 of the 5 CSTD systems, residue from HD-contaminated vials spread as the vial was handled in a pharmacy environment. HD contamination transferred initially to pharmacy PPE, then spread to ancillary products such as IV bags, IV sets, and transport bags, which, in turn contaminated nursing PPE…" As this study demonstrates, cross-contamination can occur even with the use of CSTDs. This study also supports the USP Commentary statements related to this area that were previously noted in staff recommended responses. Photos included in Figure 1 clearly show the contamination of gloves. Staff note that compounding personnel must demonstrate competency in aseptic techniques routinely. Further while the changing of gloves may

[3] Hazardous Drug Contamination of Drug Preparation Devices and Staff: A Contamination Study Simulating the Use of Chemotherapy Drugs in a Clinical Setting, Hosp Pham, 2017 Aug, 20;52(8): 551-558, Accesed in NIH National Library of Medicine

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			failed in its obligation to make an initial economic impact determination that is "supported by facts or evidence".	potentially create an opportunity for microbial contamination, those risks can be mitigated. Mitigation strategies can be developed by facilities based on their likely risks. Further, Board staff note that the commenter is asserting that the Board has failed to meet the requirements of the APA. Board staff disagree with this comment and note that under the APA the Board is required to respond to all comments received. The Final Statement of Reasons is the document used to memorialize the Board's response to each of the comments received. All comments, however, have also been made available during board discussions of this issue. There is no requirement for the Board to cite empirical data as part of its rulemaking. Rather, the Board is required to cite empirical data when such data is relied upon. The Board includes refence to documents relied upon in its Initial and Modified Statement of Reasons and elsewhere in the rulemaking, which include for example the minutes from public discussions where cost issues could have been raised. Specifically related to the cost of gloves, staff note that costs may vary depending on the types of

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				HD gloves, sterile versus nonsterile, and vendors used. The Chapter determines the types of gloves that must be used depending on the functions being performed and establish a number of requirements for changing gloves. Such costs are related to provisions of the Chapter, not the Board's regulations. Inspections performed by staff reveal a variation in how facilities operationalize requirements related to donning gloves when compounding hazardous preparations. Inspectors note that in many inspections compounding personnel are using two pairs of sterile gloves and changing the outer gloves in between hazardous preparations as a means to mitigate the potential for cross-contamination. These inspection findings demonstrate that this practice is already occurring in a variety of settings. It is important to note that the Board may establish requirements for a myriad of reasons related to consumer protection and based on a variety of information sources, including observations made during past investigations or inspections, best practices, based on information from experts and other regulatory

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				agencies, including for example the FDA and USP. Although the Board did not receive any significant comments on costs throughout the development of the rulemaking that occurred over a series of public meetings, the Board independently identified and reported costs including for SOP development and review (using the estimated time and the BLS pharmacy salary from May 2022) incubator cleaning and calibration cost estimates, estimates for hazardous plastic containers, costs for disposable mats, etc. Costs could vary greatly as the practice of compounding varies greatly, for example, some facilities only engage in nonsterile compounding, where other facilities may engage in all types of compounding. Further, some facilities are already, as a standard of practice, changing gloves consistent with both the requirements of the Chapter as well as the Board's proposed regulations. The Board did not include estimated costs associated with compliance with other legal requirements (e.g. federal requirements, title 22, building

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				code, etc.) nor did it include costs incurred to comply with provisions of USP (for examples costs to perform testing, training etc.) Costs that were identified by the Board were estimated for each license issued based on all factors. If an entity owns more than one license, their costs could increase based on the number of licenses held. Presumably the costs incurred could be spread over various licenses with policies and procedures for example being shared. Although cost related to gloves was not raised during the public meetings where text was developed, costs related to glove requirements were raised during the formal comment period where the Board received specific comments regarding the cost of gloves. The Board's second modified text in 1737.7(c) reflect the change that could reduce the overall cost related to gloves without compromising patient safety. Staff further note that the Chapter establishes provisions for changing gloves and where the Chapter requires the use of and changing of gloves, such costs are a function of compliance with the Chapter, not the Board's regulation. Staff further note that costs for compliance with the minimum

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				standards of the regulation should not be conflated with costs incurred by a facility and how it chooses to operationalize the requirement. As an example, the costs for a facility that elects to compound a single type of HD such as methotrexate for multiple patients before changing to compound a different type of HD preparation would most likely have a lower cost than a facility that does not operationalize the requirements in the same manner. Further, the types of HD compounding performed (e.g. hazardous versus nonhazardous, sterile versus nonsterile) would also factor into costs. It is important to highlight that some of the changes in the proposed regulation text could also result in cost savings to facilities, such as provisions that allow for the transfer of some training from one location to another and increased provisions for immediate use.
13	1737.7(c)	CSHP	The board did not demonstrate that it understood and considered the comment in that it only responded to our comment regarding CSTD's. the board did not demonstrate that it understood and considered the comment the risk to staff created via repeated change of outer gloves. The board did not demonstrate that it understood and considered the comment regarding the increase in waste. The board did not demonstrate that it understood and considered the comment regarding the inappropriateness of the use	Board staff have reviewed the comment and do not recommend any changes to the proposed text based on these comments. Staff note that the commenter appears to be suggesting that

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			of online prices for gloves. 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. The board did not demonstrate that it understood and considered the comment regarding contracting and the difference in pricing available to pharmacies. 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. 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. 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 or compromising the inner glove. This could lead to reduced protection, especially when handling hazardous drug compound. Frequent removal and disposal of outer glove changes creates significant waste. 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 an 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, 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. 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	interested parties did not have an opportunity to previously engage with the Board on the development of the regulations or provide information on potential cost impacts to the Board's regulations. Board staff note that the public record in this matter demonstrates that interested stakeholders were provided numerous opportunities to engage with the Board through the regulation development process and through the rulemaking process, which included numerous opportunities to provide both written and oral public comments on the draft proposals, including costs. As an example, during the April 2023 Enforcement and Compounding Committee, public comment suggested an increase in the cost of care stemming from the proposed requirement to use preparation mats which at the time was proposed in CCR Section 1737.13. Based on the comments received, at that time, changes were made to the language to clarify the requirements and address in part the cost issue while balancing patient protection. During this same meeting, the Board's proposed regulations related to the changing of outer gloves was discussed. Record of this meeting reveal that no additional public

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			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. Yet, board staff's comments regarding this section and others reflects a high level of misguided confidence in the ability to determine impacts on the topic of economics at a level sufficient to make such determinations. We would like to invite the board to engage with CSHP and our health system leaders with the knowledge, experience, and expertise to gather the true economic impact of this proposal. **Recommendations**: We once more reiterate the comments by both us and others at various stages through this rulemaking process that USP has sufficient standards to promote and protect patients and this regulation fails to demonstrate its expected enhancement of patient safety efforts. Delete the proposed language: ~~**(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.**~~	comments were made related to costs. It is important to note that during the formal rulemaking process in response to comments received, the Board further modified requirements related to the use of preparation mats, making such use permissive. Again, in response to comments related to costs. In addition, the Board updated its proposed language related to minimum requirements for changing gloves, removing the requirement to change every 30 minutes. The Board staff further note that the Board routinely encourages public participation in its meetings and include a policy that encourages written comments. The Board's proposed regulation establish minimum requirements for compounding. The Board does not mandate how these requirements will be operationalized. Workflows, compounding practices, staffing and other business decisions many times drive the costs for an organization.
14	1737.7(d)	Marie Cottman	This is a ***non-functional*** rule for facilities designed with a designated HD anteroom connected to a C-SEC HD Buffer Room. In practice, without pass-throughs (which are frowned upon), the compounder may need to return to the anteroom between compounds for additional supplies or to remove excess materials from the work area.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Board staff are not clear on the comments.

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			An anteroom as defined by USP, is a transitional area for activities that generate particles (such as doffing) A) If the compounder must doff in the C-SEC, then the ungowned/dirty compounder will re-enter the "clean side" of the anteroom ungarbed thus eliminating the possibility of a clean and dirty side to the HD ante room (which is still required in USP)! B) Doffing as required in this proposed rule will generate an unnecessary particulate load to the C-SEC increasing the risk of contamination as doffing is an activity that produces a lot of particulates! C) It is unreasonable to require doffing within the C-SEC when the facility has a dedicated HD anteroom. D) If this remains in place, in an effort to avoid doffing and wasting gowns (in HD, gowns cannot be reused) compounders may take in too many materials at one time increasing an opportunity for errors. USP 800 states (emphasis added) "Although ***not*** a recommended facility design, ***if*** the negative-pressure HD buffer room is entered through the positive-pressure ***non***-HD buffer room, the following is also required: • A line of demarcation must be defined within the negative-pressure buffer room for donning and doffing PPE" This is the ONLY situation to require doffing within the buffer room (aka C-SEC). USP 797 states "The area within 1 m of the PEC should be dedicated only for sterile compounding (e.g., not storage, hand hygiene, donning and doffing garb, or other highly particle-generating activities such as patient care)." **I recommend that you remove section 1737.7(d) and allow USP 800 section 5.3.2 to stand as written.**	Board staff would refer the commenter to the Chapter and the related USP FAQs. For example, FAQs 52 & 53 provides additional information related to this issue.
15	1737.8	Marie Cottman	The expanded statement about crushing or splitting tablets is not included, but seems appropriate for sections 1737.8	Board staff have reviewed the comment and do not recommend a change in the proposed text. Staff note that the Board's regulation text establish minimum standards and have determined that provisions for a hazardous drug communication

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				plan does not need to extend to "crushing or splitting tablets.". Staff remind the commenter to review CalOSHA requirements.
16	1737.11(b)	Marie Cottman	This is limiting. Impervious plastic chemo bags have "CHEMOTHERAPY" printed on the bag. Would we be required by this proposed rule to ALSO add a label that says HAZARDOUS DRUGS?? **Recommend to add "or Chemotherapy" to this wording.** (b) All compounded antineoplastic HDs shall be transported from the facility in an impervious plastic container and labeled as Hazardous Drugs or Chemotherapy on the outside of the container.	Board staff have reviewed the comment and believe a change to the proposed text may be appropriate to clarify that a second label is not required if the hazardous label is available through the outer container. Board staff offer the following recommendation. 1736.11 (b) All ~~HD APIs and~~ compounded antineoplastic HDs shall be transported from the facility in an impervious plastic container and labeled as Hazardous Drugs ~~HD~~ on the outside of the container **unless the label is visible through the outer container**.
17	1737.12	Marie Cottman	But what if the equipment is being used for the same HD, different strength? For example, Progesterone capsules. First preparation is progesterone 5mg capsule, second preparation is progesterone 50mg capsule. Decontaminating the capsule plates is a process that involves wetting the plates. This will prevent further compounding using that equipment for no less than an hour. (capsules melt when exposed to liquids– the plates must be 100% dry!) **Recommend wording change to allow for equipment to be used without full decontamination for the same HD.** Equipment used in nonsterile HD compounding shall be dedicated for use with HDs and shall be decontaminated ~~after each use~~.prior to use with a different HD and at the end of the shift.	Board staff have reviewed the comment and do not recommend a change based on the proposed text. Board staff note that comments provided in this area appear new. The Board's proposed text is based on the recommendation from the Chapter to perform decontamination after every use.

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			The expanded statement about crushing or splitting tablets is not included, but seems appropriate for sections 1737.12	
18	1737.13(a)	Marie Cottman	a) Changing the mat if a spill occurs is already required in section 13, USP 800. b) It is excessive and wasteful to change the mat when no spill or contamination is present. Sterile prep mats cost ~$3.00 each. In addition to the expense, the change in process for all sterile compounders might result in a shortage of mats because the use will not double, but it might increase by 10 or 20 fold! c) If you have to spell out that the mat has to be removed at the end of the compounding activity, likely your compounders are not cleaning! (you cannot clean the PEC if there is a mat in it!) IF you cannot provide evidence of the NEED (not assumption) to change the mat for EVERY preparation, then **Recommend to remove.**	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Board staff note that the Chapter provides permissive language related to the changing of mats. Staff further note that nothing in the Board's regulation text requires the use of a mat, rather it establishes the provisions where a facility determines that the use of disposable mats is appropriate.
19	1737.14(b)	Marie Cottman	This is poorly phrased. Gloves to not allow for appropriate administration or disposal of the HD. Gloves are merely used to handle the compound during administration or disposal. **Recommend to reword:** (b) When dispensing a compounded antineoplastic HD to a patient or patient's agent, the pharmacy shall provide, or offer for purchase, a sufficient supply of ASTM D-6978 standard chemotherapy gloves, to allow for appropriate ~~administration,~~ handling~~, and disposal~~ of the HD during administration and disposal. A compounded antineoplastic HD preparation that is administered to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code is exempt from this requirement.	Board staff have reviewed the comment and believe changes to the proposed text may be appropriate to provide clarity of the language. Board staff offer the following change. (b) When ~~furnishing~~ dispensing ~~an~~ a compounded antineoplastic HD to a patient or patient's agent, **the pharmacy shall provide, or offer for purchase, ~~,~~** a sufficient supply of ASTM D-6978 standard **chemotherapy** gloves, ~~that meet the ASTM D-6978 standard~~**, ~~and shall be provided to the patient or the patient's agent~~**, to allow for appropriate **~~administration,~~**

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				handling, and disposal of the HD. ~~drugs by the patient or the patient's agent shall be provided.~~ **A compounded antineoplastic HD preparation that is administered to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code is exempt from this requirement.**
20	1737.15	Marie Cottman	The expanded statement about crushing or splitting tablets is not included, but seems appropriate for sections 1737.15.	Board staff have reviewed the comment and do not recommend a change in the proposed text. Staff note that the Board's regulation text establish minimum standards and that specific provisions for deactivating, decontaminating, cleaning and disinfecting do not need to extend to "crushing or splitting tablets." Staff remind the commenter to review CalOSHA requirements.
21	1737.15(a)	Kaiser Perm	Deactivating, decontaminating, cleaning, disinfecting, and sporicidal agents shall be used in accordance with manufacturers' specifications, or subsequent ~~manufacturer approved~~ published studies, and shall be surface compatible. We appreciate the modifications that the Board made to the proposed regulation based on the recommendation in our December 6, 2024 comment letter. However, we are concerned that the phrase "manufacturer approved studies" is likely to limit the usefulness of this flexibility. Manufacturers are only likely to approve/sanction a study if they perceive both potential scientific and financial benefits associated with the study. Conversely, if a manufacturer believes that a study is a threat to one or more of their products, they may be less likely to support a study. Contrast that with	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that the commenter's change would not require nor establish any baseline for published studies that could be relied upon. For example, if the Board accepted the proposed regulation text, an entity could perform a study and publish in its own newsletter and such action would comply with the suggested text.

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			the motivations of academic institutions and healthcare organizations that do not have the same financial incentives as a manufacturer. Therefore, we recommend changing the phrase "manufacturer approved studies" to "published studies" to ensure that published studies that are unrelated to a manufacturer may be used to support the selection of an alternative agent for deactivating, decontaminating, cleaning, disinfecting, and or and/or killing bacterial and fungal spores in the compounding suite.	
22	1737.16	Marie Cottman	The expanded statement about crushing or splitting tablets is not included, but seems appropriate for sections 1737.16.	Board staff have reviewed the comment and do not recommend a change in the proposed text. Staff note that the Board's regulation text establish minimum standards and that specific provisions for spill control do not need to extend to "crushing or splitting tablets.". Staff remind the commenter to review CalOSHA requirements.
23	1737.17(a), (b), and (c)	Marie Cottman	This is overly repetitive and poorly worded. **Recommend to consolidate and renumber.** (a) A facility shall maintain and follow written SOPs <u>that include at least the following</u> for all situations in which HDs are compounded or crushing or splitting tablets or opening capsules of antineoplastic HDs is performed. ~~(b) A facility where compounding of HDs is performed or where crushing or splitting tablets or opening capsules of antineoplastic HDs is performed shall have SOPs that include at least the following:~~ (1) Hazard communication program (2) Occupational safety program (3) Designation of HD areas, if compounding (4) Receipt, if compounding (5) Storage, if compounding (6) Compounding, if applicable (7) Use and maintenance of proper engineering controls (e.g., C-PECs, C-SECs, and CSTDs), if applicable	Board staff have reviewed the comment and do not recommend changes to the proposed text. The commenter appears to be recommending nonsubstantive changes to the proposed regulation text.

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			(8) Hand hygiene and use of PPE based on activity (e.g., receipt, transport, compounding, manipulation, administration, spill, and disposal), as applicable (9) Deactivation, decontamination, cleaning, and disinfection (10) Dispensing, if applicable (11) Transport, if compounding (12) Administering, if applicable (13) Environmental monitoring (e.g., wipe sampling), if compounding (14) Disposal, if compounding (15) Spill control, if compounding (16) Medical surveillance, if compounding ~~(c)~~ (b)The pharmacist-in-charge, professional director of a clinic, or designated representative-in-charge, as applicable, shall work with the facility's designated person to ensure SOPs are reviewed at least every 12 months and this review is documented. Documentation of compliance with ~~the~~ this subdivision shall be maintained for three years.	