Section	Commenter	Comment	Staff Response
1737	Cal/OSHA	Cal/OSHA is concerned that the proposed regulations partially duplicate but are less protective than certain Cal/OSHA regulations for employee health and safety. These parallel standards may in turn create confusion for the regulated community, which may comply with the less stringent and less protective regulation. Additionally, as drafted, the regulation may interfere with a statutory requirement under labor code 144.8 for Cal/OSHA to develop a regulation for the safe handling of anti-neoplastic drugs. Cal/OSHA recommends the addition of a note reading: **Additional safety and health requirements are included in the California Code of Regulations, Title 8 and enforced by the Division of Occupational Safety and Health.**	Board staff have reviewed the comment and believe that a reminder to licensees of the additional requirements under the purview of Cal/OSHA may be appropriate. Board staff recommend the inclusion of the requested language at the beginning of Article 4.7 1737. Handling of Hazardous Drugs. This article applies to the handling compounding of Hazardous Drugs (HDs) or performing "other manipulations" included in Table 1 of the Chapter of antineoplastic HDs, of Hazardous drugs established by United States Pharmacopeia (USP) General Chapter 800 (USP 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. **(a)** A licensee performing hazardous drug (HD) compounding shall comply with this article as well as the non-sterile and sterile compounding requirements, as applicable, in Article 4.5 and Article 4.6. **(b) Additional safety and health requirements are included in the California Code of Regulations, Title 8 and enforced by the Division of Occupations Safety and Health.**
1737.1	Assoc of NorCal Oncologists and Medical Oncology Assoc. California Rheumatology Alliance CA Medical Association CalDerm	We are concerned that the proposed regulations will require a pharmacist to be present during these types of activities, which would be an onerous burden on community sites of care, particularly those in rural settings. ANCO and MOASC are concerned that these proposed regulations, if adopted, would result in cancer patients being forced to obtain their chemotherapy at a hospital or infusion center, which would place new burdens on patients who are already fighting for their lives. § 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. 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 Professions Code) with respect to its licensees. It may be appropriate for the commenter to confer with their licensing board to discuss their concerns. Board staff note that the Medical Board of California has

Section	Commenter	Comment	Staff Response
			previously provided a written response to individuals inquiring about the applicability of the Board of Pharmacy's regulations to individuals and practices that operate under the jurisdiction of the Medical Board of California. Below is the information provided from the Medical Board - - Dear Ms. Sodergren: I understand that some concerns have been raised by stakeholders about the applicability of the Board of Pharmacy's pending compounding regulations to licensees of the Medical Board of California (MBC). Existing statute (see Business and Professions Code (BPC) section 2220.5) makes it clear that only the MBC can discipline its physician licensees. Whenever a physician is engaging in compounding (or any other action that their medical license authorizes them to perform) they must always do so consistent with the standard of care. For the purposes of MBC's enforcement program, the standard of care is established by expert testimony in the context of the facts and circumstances of a specific case. It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding, especially since some of the proposed regulations reflect what is already required for physician compounding under federal law, including, but not limited to, Section 503A of the Federal Food, Drug, and Cosmetic Act (BPC section 2225(b) allows MBC to investigate violations of federal law related to the practice of medicine). Feel free to share this message with others as you see fit who might also be concerned about the applicability of their pending regulations to the physician community. Please contact me if you have any further questions. Sincerely, Reji Varghese

Section	Commenter	Comment	Staff Response
1737.2(a)	Stanford Health Care	**Comment:** For a large health system pharmacy department, it is common for multiple people to assume the responsibilities of the designated person. Additionally, proposed sections 1735 and 1736 define the designated person(s) as "one or more individuals." The USP <800> FAQ further supports this by clarifying that the designated person may be more than one person. **Recommendation:** Revise language to allow the designated person for hazardous drug handling to be "one or more individuals."	The Board staff have reviewed the comment and recommend a change to the proposed regulation text based on the comment and other comments received related to this section. Recommended language is below: 1737.2(a) The facility's list of HDs as required by USP Chapter 800 must be reviewed and approved by **the** ~~**designated person and**~~ the pharmacist-in-charge (PIC), **or the** professional director of a clinic, or **the** designated representative-in-charge, as applicable. **Approval shall be documented at least every 12 months.** **(1) In a pharmacy, T**~~**t**~~he designated person**(s)** must be ~~**a single individual**~~ approved by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the handling of hazardous drugs. The designated person**(s)** shall not exceed the scope of their issued license. When **a** ~~**the**~~ designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the judgment of a pharmacist. ~~**Approval shall be documented at least every 12 months.**~~
1737.2(a)	CSHP	It must be noted that the PIC is responsible for compliance but need not to be doing all the work associated with following these laws. PIC's must be able to delegate operational and administrative matters according to their professional discretion. Pharmacists are practicing professionals, and this is associated with making many important patient care and operational decisions. (a) The facility's list of HDs as required by USP Chapter 800 must be reviewed and approved ~~by the designated person and the pharmacist-in-charge (PIC)~~ or designee~~, professional director of a clinic, or designated representative-in-charge, as applicable. The designated person must be a single individual approved by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and~~	Board staff have reviewed the comment. Board staff have concerns with the proposed change offered by the commenter, but note that a separate commenter has offered a recommendation that preserves the policy goal of the Board while balancing what the Board understands may be, at least in part, the concerns of the commenter. Board staff recommend the following change. Staff note that a designated person is not required to be a pharmacist. 1737.2(a) The facility's list of HDs as required by USP Chapter 800 must be reviewed and approved by ~~**the designated person and**~~ the pharmacist-in-charge (PIC), **or the** professional director of a clinic, or **the** designated representative-in-charge, as applicable.

Section	Commenter	Comment	Staff Response
		~~personnel as related to the handling of hazardous drugs. The designated person shall not exceed the scope of their issued license. When the designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the judgment of a pharmacist.~~ And this approval shall be documented at least every 12 months. (b) If an assessment of risk approach is taken as authorized in USP Chapter 800, it shall be approved ~~by the designated person and the pharmacist-in-charge~~ or designee~~, professional director of a clinic, or designated representative-in-charge, as applicable~~.	**~~Approval shall be documented at least every 12 months.~~** **~~(1) In a pharmacy, T~~**the designated person**~~(s)~~** must be **~~a single individual~~** approved by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the handling of hazardous drugs. The designated person**~~(s)~~** shall not exceed the scope of their issued license. When **a ~~the~~** designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the judgment of a pharmacist. **~~Approval shall be documented at least every 12 months.~~**
1737.2(a) and (b)	Cedars-Sinai Torrance Memorial	Often times, the designated person may be the pharmacist-in-charge. Recommend revising the language to allow the Pharmacist-in-charge or designated person to review and approve the facility's list of HDs annually. CCR 1737.2(a): The facility's list of HDs as required by USP Chapter 800 must be reviewed and approved by the designated person ~~and~~ or the pharmacist-in- charge (PIC), or professional director of a clinic, or designated representative-in-charge, as applicable. The designated person must be a single individual approved by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the handling of hazardous drugs. The designated person shall not exceed the scope of their issued license. When the designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the judgment of a pharmacist. Approval shall be documented at least every 12 months**.** *CCR 1737.2(b):* If an assessment of risk approach is taken as authorized in USP Chapter 800, it shall be approved by the designated person ~~and~~ or the pharmacist-in-	Board staff have reviewed the comment and do not recommend a change based on the comment. Staff note that a designated person is not required to be a pharmacist. Staff are recommending changes to the proposed text to clarify the requirement. 1737.2(a) The facility's list of HDs as required by USP Chapter 800 must be reviewed and approved by **~~the designated person and~~** the pharmacist-in-charge (PIC), **or the** professional director of a clinic, or **the** designated representative-in-charge, as applicable. **Approval shall be documented at least every 12 months.** **(1) In a pharmacy, T**the designated person**(s)** must be **a single individual** approved by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the handling of hazardous drugs. The designated person**(s)** shall not exceed the scope of their issued license. When **a ~~the~~** designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the judgment of a pharmacist. **~~Approval shall~~ be documented at least every 12 months.**

Section	Commenter	Comment	Staff Response
		charge, or professional director of a clinic, or designated representative-in-charge, as applicable.	
1737.2(b)		Often times, the designated person may be the pharmacist-in-charge. Recommend revising the language to allow the Pharmacist-in-charge or designated person to review and approve the facility's list of HDs annually. *CCR 1737.2(b):* If an assessment of risk approach is taken as authorized in USP Chapter 800, it shall be approved by the designated person ~~and~~ or the pharmacist-in- charge, or professional director of a clinic, or designated representative-in-charge, as applicable.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that a designated person is not required to be a pharmacist. Staff are recommending changes to the proposed text to clarify the requirement.
1737.5(c)	John Gray Kaiser UC San Diego CSHP Torrance Memorial Kaweah Health	~~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 pass-through is not allowed between the hazardous drug buffer room C-SEC into an unclassified space.~~ We appreciate the Board's reference to the restriction on pass-throughs from a hazardous buffer room to unclassified space in the California Building Code. Because existing state regulations already address this restriction, we encourage the Board to delete this provision from the proposed regulations. While we recognize that the Board cannot change the requirement in the Building Code, we continue to believe that a restriction on pass-throughs from a hazardous buffer room to unclassified space is misguided. Undoubtedly, increased human traffic in and out of the buffer room presents the greatest risk of microbial contamination and migration of Hazardous Drug (HD) residues. A properly configured pass-through that is used appropriately is a commonsense tool to mitigate these risks.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text based on the comment received. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and unclassified spaces in the HD environment. The proposed text provides a delay in implementation to allow for the facility to develop the process to operationalize the requirements.
1737.5(c)	Keck/USC UC Health	The prohibition on the presence of a pass-through between a C-SEC and unclassified space has not been a requirement in USP 797 nor USP 800 and would be a new mandatory requirement for pharmacies, if passed. The approval of this requirement will place extreme hardship on existing facilities that were compliant with applicable codes at the time of construction. Cleanroom designs were approved, and compounding	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text based on the comment received. Staff note that California Code of Regulations, Title 24, Section 122.149 prohibits a passthrough between classified and unclassified spaces in the HD environment.

Section	Commenter	Comment	Staff Response
		pharmacies were licensed by the CA board and CDPH. Given extremely high cost of cleanroom re-design, construction and modifications, this requirement may lead to pharmacy closures, negatively affecting patient access to care. **Per USP 800**, " Although not a recommended facility design, if the negative-pressure HD buffer room is entered though the positive-pressure non-HD buffer room, the following is also **required: …** A method to transport HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room to minimize the spread of HD contamination. **This may be accomplished by use of a pass-through chamber between the negative-pressure buffer area and adjacent space.** The pass-through chamber must be included in the facility's certification to ensure that particles are not compromising the air quality of the negative-pressure buffer room." **Recommendation**: The BOP is asked to reconsider requiring this standard not specified in USP 800, or otherwise providing for a process to allow the presence in existing construction (e.g., grandfathering). For example: "(c) A pass-through is not allowed between the C-SEC into an unclassified space in cleanrooms if constructed after [insert date]." "Where an existing pass-through is already installed between the C-SEC into an unclassified space, the doors must be gasketed and interlocking and the pass-through must be included in the facility's certification"	The proposed text provides a delay in implementation to allow for the facility to develop the process to operationalize the requirements.
1737.5 (d)		"Where an existing pass-through is already installed between the C-SEC into an unclassified space, the doors must be gasketed and interlocking and the pass-through must be included in the facility's certification"	The Board staff have reviewed the comment that appears to be related to CCR 1737.5(c)and do not recommend a change to the proposed regulation text based on the comment received. Staff note that California Code of Regulations, Title 24, Section 122.149 prohibits a passthrough between classified and unclassified spaces in the HD environment. The proposed text provides a delay in implementation to allow for the facility to develop the process to operationalize the requirements.

Section	Commenter	Comment	Staff Response
1737.5(e)	Walgreens	This proposed requirement exceeds the standards listed in USP <800> 5.3. Additionally, CAG-003 specifically only applies to the Certification of Sterile Compounding Facilities. This reg applies it broadly to all healthcare settings compounding hazardous materials. We request this language is removed to prevent further confusion and ensure alignment with USP guidelines.	Board staff have reviewed the comment and believe the commenter is referring to 1737.5 (f) and appreciate the commenter highlighting the issue. Based on the comment received staff believe a change to the proposed text is appropriate. (~~e~~f) Where sterile hazardous compounding is performed **F**~~f~~acility room pressure monitoring equipment shall be placed consistent with CETA Guidelines CAG-003:2022. SOPs shall address corrective and remedial actions in the event of pressure differentials ~~and air changes per hour~~ excursions.
1737.6(a)	Cedars-Sinai Torrance Memorial Donald Cottman Wedgewood Pharmacy	USP 800 only recommends performing environmental wipe sampling for HD surface residue routinely. Currently, there is currently no standard for acceptable limits for HD surface contamination. Additionally, requiring additional sampling will add an undue burden to test without any concrete actionable limits. Request the board to consider removing the section or revise language to "should" to be consistent with USP 800 Chapter and to provide guidance on the specific requirement such as action level, frequency what to do when actionable levels have been reached as there is no standards provided. ***CCR 1737.6 Environmental Quality and Control*** *a) The SOPs of a premises where HDs are handled shall should address environmental wipe sampling for HD surface residue, its frequency, areas of testing, levels of measurable contamination, and actions when those levels are exceeded.*	Board staff have reviewed the comment recommend a change to the proposed text to provide clarity on the intent of the language. Staff note that the proposed regulation text does not require a facility to perform environmental wipe sampling with any specified frequency. Rather, the proposed text requires the facility to develop SOPs that include provisions for wipe sampling. It is incumbent upon the PIC (or their designated person) to use their professional judgment to determine when or if wipe sampling occurs and under what conditions. 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 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.**
1737.6(a) and (b)	Keck/USC	Environmental quality and control utilizing wipe sampling for hazardous drug surface residue is not a mandatory requirement in USP 800. While this is a	Board staff have reviewed the comment. It appears the commenter may be referring a prior version of the proposed regulation text. Staff note that the proposed

Section	Commenter	Comment	Staff Response
	Alliance for PHY Compounding	worthwhile effort that pharmacies compounding hazardous drugs should follow, there are several significant barriers that arise when this requirement is made mandatory. Per USP 800, "*there are currently no certifying agencies for vendors of wipe sample kits.*" **Recommendation**: The Board's proposed requirement to establish an environmental wipe sampling cannot be justified given several significant concerns and barriers listed above. We recommend the Board considers removing the proposed additional requirements and follow the standards outlined in USP 800 as it related to this section.	regulation text does not require a facility to perform environmental wipe sampling with any specified frequency. Rather, the proposed text requires the facility to develop SOPs that include provisions for wipe sampling. It is incumbent upon the PIC (or their designated person) to use their professional judgment to determine when or if wipe sampling occurs and under what conditions. 1737.6. **The premises shall consider environmental wipe sampling** and SOPs **~~of a premises~~** ~~where HDs are handled~~ shall **~~address~~ describes 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**.
1737.7(b) & (c)	Walgreens	Walgreens requests clarity on what defines "different" in subsection (c). For example, if a pharmacist is compounding back-to-back progesterone creams, are those considered different and would require a change in gloves? If so, then c and b in combination will create confusion. We suggest that the board adds language to clarify that their intent is for gloves to be changed when active ingredients are different between compounds, but not necessarily between every compound made.	Board staff have reviewed the comment and appreciate the commenter seeking clarification of the language. Board staff believe the following language is appropriate to further clarify "between each different HD preparation." (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.**
1737.7(c)	John Gray Kaiser Stanford Health Care UC San Diego CSHP Walgreens	Commenters request that the requirement for changing outer gloves be removed as it will result in significant increases in costs and generation of HD waste. Additionally, there is likely minimal benefit if a pharmacy is using CSTDs for HD compounding. Remove language to be consistent with USP 800 or revise language to require changing outer HD gloves, between each different HD preparation, if compounding is performed without a CSTD. Or gloves should only be changed between each different HD API preparation and if there is a gap between the compounding of those products.	The Board staff have reviewed the comment and do not recommend a change to the proposed regulation text based on the comment received. As the cited research demonstrates, while the CSTD does REDUCE the risk of contamination, it does not eliminate it. The Board appreciates the use of the technology as an important safety measure and notes the following from USP. 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."

Section	Commenter	Comment	Staff Response
1737.7(c)	Cedars-Sinai Torrance Memorial UC Health	Many health-systems use closed system transfer device (CSTD) when compounding antineoplastic HDs. The use of CSTD has shown to significantly reduce overall chemical contamination (12.24% vs. 26.39%). 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. **Recommendations**: *Revise the proposed language to:* (c) Outer gloves used for HD compounding shall be changed between each different HD preparation if a closed system transfer device (CSTD) is not used.	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. 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."
1737.7(c)	Donald Cottman	Given the vast efforts made to prevent contaminating events, such as using closed-system-transfer-devices, the occurrence of any actual contamination is extremely low. Requiring a compounder to change gloves between different HD preparations defies logic. If a compounder is handling product A and there is a suspicion, or assumption, of exposure precluding them from handling product B, what is the logic that is ok to handle product A-2? Would not item A-2 be just as contaminated as product B? Should not avoiding contamination of product A-2 be of the same priority as preventing contamination of product B? If we reject the presumption that gloves are inherently contaminated by engaging in compounding, then having regulations that require them to be changed between HD drugs is arbitrary and nonsensical. This regulation should be deleted, or restated to say changing of gloves should be done when contamination is suspected.	Board staff have reviewed the comment and disagree with the commenter suggesting that compounders should assume that gloves are not contaminated. Board staff note that the Chapter states, "Consider all PPE worn when handling HDs to be contaminated with, at minimum, trace quantities of HDs. PPE must be placed in an appropriate waste container and further disposed of per local, state, and federal regulations. PPE worn during compounding should be disposed of in the proper waste container before leaving the C-SEC. Chemotherapy gloves and sleeve covers (if used) worn during compounding must 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."
1737.7(d)	Donald Cottman	The C-SEC if the physical space the PEC is located, also known as the buffer room. This is under positive pressure	Board staff have reviewed the comment and disagree with the commenter. Board staff note that the Chapter

Section	Commenter	Comment	Staff Response
		from the ante-room, which has HEPA filtered air feeding into it, so that only HEPA filtered air is pushed into the buffer room. As written, this requires PPE be removed inside the buffer room, leaving a person standing inside the buffer room, with exposed skin and clothing. This creates a profound risk of contamination of the C-SEC buffer room by having un-gowned personnel in that space. This defies all logic for clean-room particle reduction practices. The assumption being proposed is that the PPE worn by the staff is inherently contaminated by the simple act of compounding HD drugs, regardless of all containment efforts being employed, such as biologic safety cabinets and closed system transfer devices. In this assumption scenario, it is logical that garb should be removed in a negative pressure environment that is externally vented, which would require doffing PPE in the C-SEC buffer room. This is because the ante-room, by definition and design, is a positive pressure room with HEPA filtered air exiting into both uncontrolled space, as well as the C-SEC buffer room. Any contamination in the ante-room would be ejected into the uncontrolled space, so doffing in this space would create a risk to those outside of the ante room. However, if we make the assertion that the simple act of compounding does not contaminate a worker's PPE, given the precautions used during the process that include the PEC, CSTDs, regular cleaning of gloves, and attention to potential contamination events, then the risk of HD contaminated PPE is extremely low. In contrast, the risk of introducing microbial contamination to the C-SEC buffer room is plainly obvious if workers are removing their PPE inside the buffer room. This is a flaw in current USP <800> regulations regarding the removal of PPE in sterile HD compounding. Having an un-gowned person past the line of demarcation in the ante-room, standing un-gowned in the buffer room, is substandard practice for cleanroom protocols.	states, "Consider all PPE worn when handling HDs to be contaminated with, at minimum, trace quantities of HDs. PPE must be placed in an appropriate waste container and further disposed of per local, state, and federal regulations. PPE worn during compounding should be disposed of in the proper waste container before leaving the C-SEC. Chemotherapy gloves and sleeve covers (if used) worn during compounding must 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." Board staff note that the Board's proposed regulation text is consistent with the provisions of the Chapter while establishing a provision for the facility to operationalize the requirements through the development of its SOPs.

Section	Commenter	Comment	Staff Response
		This regulation should be rewritten to state PPE should not be removed in the C-SEC, but rather doffed in the ante-room.	
1737.9	CVS	While USP 800 does not require competency training for Table 1 manipulations, the Board's staff has determined that a portion of the Table 1 manipulations necessitate competency training, such as "withdrawing or diluting injectable HDs from parenteral containers", "expelling air or HDs from syringes", "weighing or mixing components", "constituting or reconstituting powdered or lyophilized HDs" and "crushing or splitting tablets or opening capsules". However, as written if a pharmacy partakes in any listing within Table 1, competency training must be performed. CVS Health believes that competency training for "pouring oral or topical liquids from one container to another", disposing of gloves and cleaning counting trays is overly burdensome and that safe procedures can easily be achieved via less rigorous requirements, such as through computer-based training and SOPs. CVS Health requests that the training of both the person assigned to provide training and the personnel responsible for "other manipulations of antineoplastic HDs" be determined according to professional judgment and documented within required SOPs. *In* addition to the standards in USP Chapter 800, the following requirements apply to a facility where the compounding of HDs is performed or when a facility's SOPs require training to perform certain ~~one where~~ "other manipulations" included in Table 1 of the Chapter of antineoplastic HDs ~~is performed~~. 1. *Any person assigned to provide training the training specified ~~in this Article~~ shall have demonstrated competency in the skills in which the person will provide training or observe and measure competency described in the facility's SOPs as referenced in section 1737.17. Documentation must be maintained demonstrating compliance with training* requirements, and for compounding *demonstrated~~ing~~ competency must be maintained.*	Board staff have reviewed the comment and believe that additional clarification in appropriate on the specific "other manipulations" to more clearly effectuate the Board's policy in this area. 1737.9. Personnel Training. In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed or **~~one where "other manipulations" included in Table 1 of the Chapter of~~ where crushing or splitting tablets or opening capsules of** of antineoplastic HDs is performed. ~~Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article.~~ **Note**: Additional conforming changes are necessary throughout the article to reflect this change from " 'other manipulations' include in Table 1 of the Chapter" to "crushing or splitting tablets or opening capsules" (or similar) and are reflected in the recommended proposed modified text throughout the article.

Section	Commenter	Comment	Staff Response
		2. *All personnel responsible for compounding HDs or "other manipulations of antineoplastic HDs"* for which facility SOPs require demonstrated competency *who fail any aspect of ongoing evaluation and training ~~in compounding HDs or other manipulations of antineoplastic HDs~~ shall not compound HDs or perform other manipulations until after successfully passing reevaluations in the deficient area(s), as ~~As~~ detailed in the facility's SOPs. Any failure in competency shall* comply with the provisions of 1735.2(c) or 1736.2(d), as applicable.	
1737.13(a)	Donald Cottman	The requirement that the mat be changed "after each different HD preparation" defies logic. If product A is prepared and regulation requires that the mat must be changed before making product B, then there is a presumption that there is contamination on the mat. But what is the logic that it is ok to prepare product A-2 on that contaminated mat? If there is contamination on the mat, then spreading contamination from A-1 to A-2 should not be allowed. To be consistent with logic, the regulation should be that the mat must be changed after every HD preparation. However, if it is recognized that changing a mat after every HD preparation would result in an unreasonable use of sterile mats, given that 20 mats could be used by one compounder in one compounding session, then one must reject the presumption that a mat is contaminated simply by the process of being used in HD compounding. If we reject the presumption of contamination simply by the act of compounding, then it should not matter if a mat is used for the same HD drug or a different HD drug, since there is no contamination present. This regulation should be limited to stating that the mat should be changed immediately if a spill occurs.	Board staff have reviewed the comment and believe that a mat can continue to be used under if the HD preparations are for a single patient or if the HD preparations are using the same HD ingredient. 1737.13 (a) If aA disposable preparation mat is used for compounding a CSP it must be sterile and it must be changed immediately if a spill occurs, after each different HD preparation **unless multiple preparations of the same drug or single patient is occurring**, and at the end of the daily compounding activity.shall be placed ~~on the work surface of the C-PEC when compounding HD preparations. Where the compounding is a sterile preparation, the preparation mat shall be sterile. The preparation mat shall be changed immediately if a spill occurs, after each HD drug, and at the end of daily~~ compounding activity.
1737.13(b)	Stanford Health Care	There are other effective strategies to prevent drug mix-up and cross-contamination besides limiting one HD preparation in a C-PEC at a time. These include clearly defined segregation between different HD preparations	Board staff have reviewed the comment and recommend changes to the proposed text based on the comment received. Staff note that adverse drug events have been received where two vials were being

Section	Commenter	Comment	Staff Response
		(e.g., dividers, bins, barriers), compounding multiple HD preparations of the same drug, and compounding different HD preparations for the same patient. Front-line staff have commented that there are HD drugs that take a long time to dissolve and not being able to continue compounding other medications would negatively affect patient care. This is especially true for our locations with only one or a limited number of hoods. Revise language to allow exceptions for more than one HD preparation in a C-PEC at a time under the following circumstances 3. Implemented methods that create clearly defined segregation between different HD preparations. 4. Multiple HD preparations of the same drug are being compounded. 5. Multiple HD preparations for the same patient are being compounded.	compounded at the same time. In this instance, a patient received an HD compounded for another patient. In addition, staff remain concerned about the potential risk for cross contamination. Board staff believe the following change to the language provides additional flexibility while preserving patient protections. 1737.13(b) Only one HD preparation may be handled in a C-PEC at one time~~.~~ **unless the multiple HD preparations are of the same drug or are multiple HD preparations for a single patient**.
1737.13(b)	Donald Cottman	This regulation suggests that having two HDs prepared in a C-PEC at the same time is due to the risk of cross contamination, and not microbial contamination, as there is no limitation to performing non-hazardous sterile compounding on more than one drug. If there is a presumption that the presence of HD Drug 1 contaminates the HD compounding space such that one cannot have HD Drug 2 in the same space, then regulations should require the complete cleaning and decontamination of the compounding space between each compound. This is not the case, so clearly the BOP and USP<800> do not assert that the simple act of compounding an HD drug contaminates the compounding space. If the compounding space is not contaminated by HD drug, and it is accepted practice that when using good aseptic techniques one may prepare multiple sterile compounds at the same time, in the same space, there is no logic to this restrictive regulation. This regulation should be deleted.	Board staff have reviewed the comment and recommend changes to the proposed text based on the comment received. Staff note that adverse drug events have been received where two vials were being compounded at the same time. In this instance, a patient received an HD compounded for another patient. In addition, staff remain concerned about the potential risk for cross contamination. Board staff believe the following change to the language provides additional flexibility while preserving patient protections. (b) Only one HD preparation may be handled in a C-PEC at one time~~.~~ **unless the multiple HD preparations are of the same drug or are multiple HD preparations for a single patient**.

Section	Commenter	Comment	Staff Response
1737.14(a)	CSHP	It is not clear if the interpretation of "plastic container" requires a rigid plastic container and/or if a zip-lock bag type is allowable. It is not clear if said single use zip-lock bag must be decontaminated, generally if it is a single use bag decontamination is not needed. Absent clarifying language, the proposed language could be misinterpreted and appears to require that all HD's be placed and furnished in a rigid plastic container when compounding is complete. It is recommended that the proposed language be changed to the following: (a) When furnishing a compounded antineoplastic HD for administration, the facility shall: (1) Double bag or place the HD in a decontaminated plastic container with an HD label on the outside of the bag or container; and (2) For an infused antineoplastic HD, attach and prime tubing and attach a CSTD when appropriate.	Board staff have reviewed the comment and do not recommend a change based on the comment. A facility can determine the number and type of plastic container(s) they wish to use. There is nothing in the proposed regulation text that would prevent double bagging. While reviewing the comment however, staff noted that the provisions is 1737.14(a)(1) would be better placed 1737.11, with the addition of 1737.11(c). 1737.11**(c) When furnishing a compounded antineoplastic HD for administration within a facility licensed pursuant to Health and Safety Code section 1250, the HD shall be placed in a plastic container and labeled as a hazardous drug on the outside of the container or with a label that is visible through the outside container.**
1737.14(b)	UC San Diego Torrance Memorial UC Health	In health facilities where antineoplastic HD are dispensed and administered by licensed health care professionals who are trained to handle HDs. Supplies such as ASTM D-6978 grade gloves, and HD disposal bins are readily available. Recommend adding exemption language to the current proposed language for HSC 1250 (Exempt from this requirement are health facilities, as defined in Section 1250 of the Health and Safety Code, if the prescriptions are administered by a licensed health care professional.)	Board staff have reviewed the comment and believe the requested change is consistent with the Board's policy. 1737.14(b) When furnishing dispensing an a compounded antineoplastic HD to a patient or patient's agent, **the pharmacy shall offer the patient or patient's agent,** a sufficient supply of ASTM D-6978 standard gloves, that meet the ASTM D-6978 standard**, and shall be** provide**d them upon request to the patient or the patient's agent**, to allow for appropriate administration, 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.**
1737.14(b)	Walgreens Alliance for PHY Compounding	Walgreens believes that mandating the supply of gloves for antineoplastic HD compounded products is overreaching; however, feels that the dispensing pharmacy and the administering facility should ensure that the appropriate gloves are available for administration. Often the patient or patient's agent,	Board staff have reviewed the comment and believe the requested change is consistent with the Board's policy. Board staff note that the language provided below also incorporates the exemption requested in the prior comment.

Section	Commenter	Comment	Staff Response
		such as a nurse, already has the appropriate supplies to administer the product and providing the gloves without the patient or patient's agent requesting them may be wasteful and contribute to excessive and unnecessary HD refuse and waste. **Proposed language:** (b) When furnishing dispensing a compounded antineoplastic HD to a patient or patient's agent the dispensing pharmacy must ensure a sufficient supply of ASTM D6978 gloves that meet the ASTM D-6978 standard is available and shall be provided upon request to allow for appropriate to allow for appropriate administration, handling, and disposal of HD drugs by the patient or the patient's agent shall be provided.	(1737.14(b) When ~~furnishing~~ dispensing ~~an~~ a compounded antineoplastic HD to a patient or patient's agent, **the pharmacy shall offer the patient or patient's agent,** a sufficient supply of ASTM D-6978 standard gloves, ~~that meet the ASTM D-6978 standard~~ **and shall be** provide~~d~~ **them upon request ~~to the patient or the patient's agent~~**, to allow for appropriate administration, 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.**
1737.14(b)	Wedgewood Pharmacy	Recommendation: Change "shall be provided" to "shall be made available for purchase".	Board staff have reviewed the comment and as indicated in the response to the prior comment, recommend a change to the proposed text that would in part address this comment. 1737.14(b) When ~~furnishing~~ dispensing ~~an~~ a compounded antineoplastic HD to a patient or patient's agent, **the pharmacy shall offer the patient or patient's agent,** a sufficient supply of ASTM D-6978 standard gloves, ~~that meet the ASTM D-6978 standard~~ **and shall be** provide~~d~~ **them upon request ~~to the patient or the patient's agent~~**, to allow for appropriate administration, 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.**
1737.15	Donald Cottman	There is no definition of the word "deactivation" and the regulation includes a "shall" preventing clarity on when compliance has been achieved. In every publication, from the FDA, to the EPA, to USP, there is the use of the word "deactivation" with no clarity on what it means. Even the FDA says "use of a registered oxidizing agent" where the EPA has no list of products that are registered as deactivating agent. Also, the word has no scientific meaning. An	Board staff have reviewed the comment and do not recommend any change to the proposed text. Staff note that the proposed text aligns with the language used within the Chapter. Further, staff note that "deactivation" is defined in the Chapter. Board staff note that in reviewing this comment and the Chapter, it was identified that the Board's proposed regulation title in Section 1737.15 does not fully mirror the

Section	Commenter	Comment	Staff Response
		antineoplastic agent that is "deactivated" means what? That doesn't treat cancer anymore? There is published literature showing that antineoplastic drugs, when subject to "deactivating" procedures, like heating in hydrogen peroxide solution for hours, will change their chemical structure so they are no longer the same chemical. But it turns out those new structures were more carcinogenic than the original compound. California should not participate in adding into its regulatory language the vague and undefined word "deactivate". It can still accomplish the intent of this section of the regulation section by removing the word.	USP Chapter. As such staff recommend retitling this section to the following: 1737.15. **~~Deactivation, Decontamination~~, Deactivating, Decontaminating**, Cleaning, and Disinfecting.
1737.15(a)	Kaiser	Deactivating, decontaminating, cleaning, disinfecting, and sporicidal agents shall be used in accordance with manufacturers' specifications or specifications established in published scientific studies and shall be surface compatible. There are agents that have been shown to be effective in deactivating, decontaminating, cleaning, disinfecting, and/or killing bacterial and fungal spores but for which a manufacturer does not provide instructions for such a use. We encourage the Board to amend the regulation to provide organizations the flexibility to choose an agent that has been shown to be effective in published studies in accomplishing one or more of these required activities.	Board staff have reviewed the comment. Staff recommend a change to the proposed text that will provide flexibility in the use of a specified agent, but in a more limited fashion, based upon a manufacturer's scientific studies that would support such use. 1737.15. (a) Deactivating, decontaminating, cleaning, disinfecting, and sporicidal agents shall be used in accordance with manufacturers' specifications, or subsequent manufacturer approved studies, and shall be surface compatible.
1737.17	CVS	While USP 800 does not require competency training for Table 1 manipulations, the Board's staff has determined that a portion of the Table 1 manipulations necessitate competency training, such as "withdrawing or diluting injectable HDs from parenteral containers", "expelling air or HDs from syringes", "weighing or mixing components", "constituting or reconstituting powdered or lyophilized HDs" and "crushing or splitting tablets or opening capsules". However, as written if a pharmacy partakes in any listing within Table 1, competency training must be performed. CVS Health believes that competency training for "pouring oral or topical liquids from one	Board staff have reviewed the comment and believe that additional change to the proposed text is appropriate to align with the Board's policy. Board staff recommend the following change to 1737.17(b). 1737.15 (b) A facility where compounding HDs is performed or one where **crushing or splitting tablets or opening capsules of "other manipulations"** antineoplastic HDs is performed shall have ~~The~~ SOPs ~~**for compounding or handling HDs shall**~~ that include at least the following:

Section	Commenter	Comment	Staff Response
		container to another", disposing of gloves and cleaning counting trays is overly burdensome and that safe procedures can easily be achieved via less rigorous requirements, such as through computer-based training and SOPs. CVS Health requests that the training of both the person assigned to provide training and the personnel responsible for "other manipulations of antineoplastic HDs" be determined according to professional judgment and documented within required SOPs. *(17) Training. including demonstrated competency if compounding*.	**Note**: Additional conforming changes are necessary throughout the article to reflect this change from " 'other manipulations' include in Table 1 of the Chapter" to "crushing or splitting tablets or opening capsules" (or similar) and are reflected in the recommended proposed modified text throughout the article.
1737.17(a) and (b)	Wedgewood Pharmacy	Subpoint (a) is confusingly worded as written and should be further cleaned up to clarify the intent of the Subpoint (b) seems to be saying almost the same thing as subpoint (a), but without clarifying (a) it is hard to tell. Recommendation: Either clarify language in subpoint (a) or consider consolidating subpoints (a) and (b) if	change to the proposed text in 1737.17(a) is appropriate 1737.17(a) A**~~ny~~** ~~premises~~ facility ~~engaged in the compounding or handling of HDs~~ shall maintain and **Note**: Additional conforming changes are necessary throughout the article to reflect this change from " 'other manipulations' include in Table 1 of the Chapter" to