Code Section Section (Subdivision)	Commenter	Comment	Response
1737	Scripps Health	For Hazardous drug compounding, commenters indicates the following costs will be incurred: wipe sampling will be $6,000 per biological safety cabinet per year, sterile gloves $40,000 per biological safety cabinet per year gloves for patients $188,000 per year sterile disposable preparation mats 52,000 per biological safety cabinet per year Commenter states USP is adequate to protect public health.	Board staff have reviewed the comment and are recommending change to the proposed regulation text. Staff are unclear where the suggested costs related to wipe sampling provisions would stem from. Staff note that the facility's SOP will define how and when wipe sampling will be performed. Any cost established would be a function of the facilities SOP. i.e. IF the facility's SOPs established a requirement for wipe sampling in the BSC, THEN a cost would be incurred. However, IF the SOP does not require wipe sampling in the BSC, the facility would not include those costs. Staff note that the type of glove required for BSCs are established in the Chapter, not the Board's regulation. The Board notes that its regulation text could require more frequent changing of gloves to prevent cross contamination but is recommending removal of the requirement to change gloves every 30 minutes. The Initial Statement of Reasons and Economic Impact Statement include this fiscal impact. The board did acknowledge this potential cost impact to the initial regulation text and anticipates that this further recommended change will result in additional cost savings. (Note: an online search reveals that the cost of a pair of gloves is about $.14/pair). Staff note that in response to this and other comments related to the use of preparation mats, staff is offering changes to make the use of mats discretionary. As recommended, where the mats are used, the requirement to change the mats will still exist. (Note: an online search shows that a sterile preparation mat is about $1.08/mat and a nonsterile preparation mat is about $0.74/mat)
1737	Marie Cottman Pacific Compounding	COMMENT: This is merely a reminder that provides no substance, clarity, nor does it improve protection of the public. RATIONALE: It is clear from CCR 4126.8. The compounding of drug preparations by a pharmacy for furnishing, distribution, or use in this state shall be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance. As the reference to Article 4.5 and 4.6 are not complete to all applicable rules and regulations related to HD compounding, this is not very useful and will not ensure compliance with all compounding rules and regulations. RECOMMENDATION: Remove.	Board staff have reviewed the comment and do not recommend any changes to the proposed text. As noted in the initial statement of reasons, compliance with the other articles is necessary as USP Chapter 800 does not include all end-to end aspects of hazard drug compounding.
1737.1	John Gray Kaiser Permanente	To avoid confusion about the situations in which consultation is required, the regulation should specify that consultation is only required when the HD is furnished to the patient or patient's agent. When an HD is furnished to a patient or patient's agent, In addition to providing consultation in compliance with section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning handling and disposal of an HD or related supplies furnished.	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language.

1737.1	Marie Cottman Pacific Compounding	COMMENT: This is repetitive of other regulations already in place and HD medications are NOT limited to compounded preparations. Consultation regulations should be consistent across all HD medications dispensed, Section 1707.2 should be modified rather than creating new regulations limited only to compounds. RATIONALE: Regarding "...proper use, storage..." the referenced Section 1707.2 subsections (c) and (d) both require consultation that includes proper use and storage. Disposal is not currently a consultation requirement, but CNSPs are not that different from capsules, creams, troches, and liquids that are dispensed by non-compounding pharmacies. If this is a true patient safety issue, then it should be addressed in ALL consultations, not just CNSPs. RECOMMENDATION: Remove section 1731.1 and initiate the rulemaking process to update 1707.2 for additional consultation requirements.	Board staff have considered the comment and do not recommend changes based solely on this comment. Staff note that changes to CCR 1707.2 are outside of the scope of the regulation. Should the Board seek to amend CCR 1707.2, at that time, the Board will consider if consultation should also encompass disposal information on manufactured drug products.
1737.1	CSHP	Rationale: Section 1707.2 (b)(2) does not require consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, however there are outpatient ambulatory infusions centers where CNSP is being administered by a healthcare professional. Recommendation: Would recommend the BOP to provide clarification for CCR 1737.1 in alignment with 1707.2(b)(2), and state that the regulation does not apply to CNSPs administered and dispensed to patients by a healthcare professional. Proposed Exemption Language: A pharmacist is not required by this subsection to provide consultation to a patient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code or where the compounded product will be administered by a licensed healthcare professional, except upon the patient's discharge with the compounded product.	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language.
1737.1	Melanie Horn Sutter Health	When a CSP is furnished to a patient or patient's agent, Iin addition to providing consultation in compliance with section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning handling and disposal of an HD or related supplies furnished. When a CSP is furnished to a patient or patient's agent, ~~i~~in addition to providing consultation in compliance with section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning handling and disposal of an HD or related supplies furnished.	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language

1737.1	Wendy Waldman Torrance Memorial Medical Center	Rationale: Section 1707.2 (b)(2) does not mandate consultation for inpatients of healthcare facilities licensed under section 1250 of the Health and Safety Code. However, there are outpatient ambulatory infusion centers where compounded sterile preparations (CSP) are administered by healthcare professionals. If the proposed regulation necessitates consultation for all hazardous medications dispensed and administered in an outpatient infusion center, it will impose a substantial workload on health systems to meet this requirement. Recommendation: Recommend providing clarification for CCR 1737 to specify that the regulation does not apply to compounded sterile preparations (CSPs) administered and dispensed to patients by a healthcare professional. Proposed Exemption Language: 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.	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language
1737.1	Mark Johnston CVS Health	Commenter indicates that section 1702.2(c), Duty to Consult, only lists two categories of mandatory counseling and the pending regulations would create a third. Additionally, 1707.2(d) lists seven additional categories of consultation for which a pharmacist may use professional judgment to decide when to utilize such counseling components. Commenter states that CVS believes that patients may become concerned about ingesting a drug that is termed hazardous, potentially discontinuing therapy. Therefore, we believe that counseling on hazardous drug disposal should be left to the professional judgment of the pharmacist; otherwise, we fear that this pending regulation might cause a greater public safety risk than it is attempting to solve. Additionally, disposal laws are complicated and vary by drug and by geography in California, including by counties and municipalities. Drug disposal is also regulated by the EPA and the FDA. Commenter believes the pending regulations are essentially requiring pharmacists to provide legal advice on proper disposal, for which the are not well educated. Commenter requests the following edit: In addition to the standards in the USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article. In addition to providing consultation in compliance with section 1707.2, whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall be provided to the patient and/or patient's agent concerning handling ~~and disposal~~ of an HD or related supplies furnished.	Staff have reviewed the comment and are not recommending a change to the proposed language based solely on this comment. Staff is offering recommended language to this section to more specifically describe when patient consultation is required.

1737.1	UCSF	Comments: • Section 1707.2 (b)(2) does not require consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, however there are outpatient ambulatory infusions centers where CSP is being administered by a healthcare professional where this may be interpreted to include such facilities. Recommendation: recommend modified language below CCR 1737.1 Introduction and Scope In addition to providing consultation in compliance with section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning handling and disposal of an HD or related supplies furnished <u>unless the CSP is being administered by a healthcare professional</u>.	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language.
1737.1	Tommy Mai Huntington Health	Rationale: Section 1707.2 (b)(2) does not require consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, however there are outpatient ambulatory infusions centers where CSP is being administered by a healthcare professional. If the proposed regulation requires consultation for all hazardous medication being dispensed and administered in an outpatient infusion center, this will put a significant workload impact on health-systems to comply with this requirement. Recommendation: Would recommend to provide clarification for CCR 1737 to state that the regulation does not apply to CSPs administered and dispensed to patients by a healthcare professional. Proposed Exemption Language: <u>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.</u>	Staff have reviewed the comment and agree that additional clarification to the language is appropriate to more specifically describe when patient consultation is required. Staff is offering recommended language
1737.2(a) & (b)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	Rationale: Often times, the designated person may be the pharmacist-in-charge Recommendation: 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 List of Hazardous Drugs subsections: (a) The facility's list of HDs as required by USP Chapter 800 must be reviewed and approved by the designated person ~~and~~ <u>or</u> 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. (b) If an assessment of risk approach is taken as authorized in USP Chapter 800, it shall be approved by the designated person ~~and~~ <u>or</u> 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 regulation text. Board staff note that the PIC is responsible for compliance with all provisions of Pharmacy Law, which would include the proposed regulations. Where an entity elects to also select a designated person, the responsibility for compliance with Pharmacy Law must continue to reside with the PIC.

1737.2(a)	Walgreens	We suggest that the board update this language to remove the requirement of the required approval of a facility's HD drug list by the Designated Person (DP) and the PIC, Director of a clinic, or representative in charge. The review and approval by the designated person is sufficient. The designated person can be any of those roles listed. However, we still feel that all trained team members should review the list and have access to the list. Recommended Language: 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), 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.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Board staff note that the PIC is responsible for compliance with all provisions of Pharmacy Law which would include the proposed regulations. Where an entity elects to also select a designated person, the responsibility for compliance with Pharmacy Law must continue to reside with the PIC.
1737.2(b)	Walgreens	We again ask that the word "and" be stricken. We suggest amending the language to say "or" to allow for multiple subject matter experts to have the ability to authorize the assessment of risk. There are many possible scenarios where there are not two individuals at a pharmacy who have the expertise to provide the approvals and often the pharmacist-in-charge does not have the expertise to provide the informed approval. Recommended Language: (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, 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 regulation text. Board staff note that the PIC is responsible for compliance with all provisions of Pharmacy Law which would include the proposed regulations. Where an entity elects to also select a designated person, the responsibility for compliance with Pharmacy Law must continue to reside with the PIC.

1737.2(a) and (b)	Mark Johnston CVS Health Also provided at Reg Hearing	Commenter believes the use of “designated person” within Article 4.7 should be optional and not mandatory, as a PIC should have the right to assume all “designated person” responsibilities themselves. A PIC should be able to retain responsibility and accountability for the performance and operation of a pharmacy, including the responsibilities and accountabilities that relate to the handling of hazardous drugs. Additionally, commenter states CVS uses corporate level policies and the "designated person" is a corporate person and not approved by the PIC. Commenter requests the following amendment: (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), professional director of a clinic, or designated representative-in-charge, as applicable. The designated person ~~must~~ may 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, or in the case of a chain pharmacy the designated person may be a corporate person or department, with the PIC remaining responsible and accountable for the performance and operation of the pharmacy. 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. (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, 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 regulation text. Board staff note that the PIC is responsible for compliance with all provisions of Pharmacy Law which would include the proposed regulations. Where an entity elects to also select a designated person, the responsibility for compliance with Pharmacy Law must continue to reside with the PIC. The PIC must approve a designated person.
1737.2(a) and (b)	Wendy Waldman Torrance Memorial Medical Center	Rationale: Frequently, the designated individual may be the pharmacist-in-charge. Recommendation: Suggest revising the language to permit the Pharmacist-in-charge or designated individual to review and approve the facility’s list of hazardous drugs (HDs) annually. CCR 1737.2 List of Hazardous Drugs subsections: (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. (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 regulation text. Board staff note that the PIC is responsible for compliance with all provisions of Pharmacy Law which would include the proposed regulations. Where an entity elects to also selecte a designated person, the responsibility for compliance with Pharmacy Law must continue to reside with the PIC.

1737.3	Marie Cottman Pacific Compounding	COMMENT: I agree that handling HDs is an employee safety issue, but I don't agree that licensees need another "reminder" as explained in the "Statement of Reasons." This is redundant and repetitive of what is required in CCR 4126.8. The compounding of drug preparations by a pharmacy for furnishing, distribution, or use in this state shall be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance. It is a minimum requirement of USP 800 that entities have Safe Work Practices, Ensure competency of personnel, "types of exposures" are listed in Section 3 and Table 1, and the required Hazard Communication Program outlined in Section 8 discusses the training of all of the above. RATIONALE: Chapter 800 Section 1 "Entities that handle HDs must incorporate the standards in this chapter into their occupational safety plan. The entity's health and safety management system must, at a minimum, include: • A list of HDs • Facility and engineering controls • Competent personnel • Safe work practices • Proper use of appropriate Personal Protective Equipment (PPE) • Policies for HD waste segregation and disposal " Chapter 800 Section 4 Paragraph 1. "Each entity must have a designated person who is qualified and trained to be responsible for developing and implementing appropriate procedures; overseeing entity compliance with this chapter and other applicable laws, regulations, and standards; ensuring competency of personnel; and ensuring environmental control of the storage and compounding areas." Chapter 800 Section 4 Paragraph 4. "All personnel who handle HDs are responsible for understanding the fundamental practices and precautions and for continually evaluating these procedures and the quality of final HDs to prevent harm to patients, minimize exposure to personnel, and minimize contamination of the work and patient-care environment" Chapter 800, Section 8. "Entities are required to establish policies and procedures that ensure worker safety during all aspects of HD handling. The entity must develop SOPs to ensure effective training regarding proper labeling, transport, storage, and disposal of the HDs and use of Safety Data Sheets (SDS), based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS)." RECOMMENDATION: Remove, it is redundant.	Board staff have reviewed the comment and do not recommend any changes to the language based on the comment. Staff note that as included in the Initial Statement of Reasons, the proposed regulation text ensures that all compounding personnel are aware of the types of HD exposures that may occur as referenced in the Chapter and that documentation occurs. An understanding of the types of HD exposures ensure employees understand how to avoid potential cross-contamination.
1737.5(c)	Wendy Waldman Torrance Memorial Medical Center	Rationale: USP 800 does not prohibit the use of a pass-through between a classified space and an unclassified space. However, this requirement, without an exemption for previously constructed classified areas, will impose significant financial and operational burdens on institutions that utilize a pass-through to comply with the new regulations. Recommendation: Revise language to remove the requirement and to align with USP 800 to read as follows: CCR 1737.5 Facilities and Engineering Controls: (c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. A pass-through is not allowed between the C-SEC into an unclassified space. A passthrough may be allowed if installed before [OAL insert effective date]. An existing secondary engineering control that has a pass-through that is not an interlocking device, may continue to be used if the SOPs document that two doors may not be opened at the same time.	Board staff have reviewed the comment and recommend changes to the proposed language, although not based solely on this comment. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and unclassified spaces in the HD environment. Board staff are offering recommended changes to the proposed text to align with building code requirements. Further, staff are recommending changes to establish a delayed implementation for installation of interlocking doors to allow two years to come into compliance. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same time, and the doors should be interlocking. A pass-though is not permitted between the hazardous drug buffer room and any unclassified area.""

1737.5(c)	Melanie Horn Sutter Health	USP 800 establishes that the unclassified C-SCA configuration to compound hazardous drugs. A C-SCA area is a C-SEC. The proposed standard restricts a pass through between and C-SCA which is unclassified into an unclassified space. A pass through that is gasketed and interlocking with HEPA purge type provides greater protection to facilitate reduced contamination of final CSPs from the C-SEC than frequent opening and closing of sliding doors to pass final CSPs in both a C-SCA and a classified cleanroom C-SEC. Board reasoning states "minor transfers [of gasses or vapors] may still occur and can impact the sterility of the area," but fails to scope that without a pass through the personnel must either enter the larger hands-free sliding doors and perform frequent donning and doffing of HD PPE to facilitate final CSP transfer for patient doses which significantly increases transfer risks of vapors, HD residue and particulate. Recommend removing this restriction and allowing the safe use of pass throughs to facilitate final HD CSPs to move efficiently and safely to and from the HD room in proper transport packaging. If deemed appropriate, please exclude C-SCA. Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. ~~A pass-through is not allowed between the C-SEC into an unclassified space.~~	Board staff have reviewed the comment and recommend changes to the proposed language, although not based solely on this comment. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and unclassified spaces in the HD environment. Board staff are offering recommended changes to the proposed text to align with building code requirements. Further, staff are recommending changes to establish a delayed implementation for installation of interlocking doors to allow two years to come into compliance. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same time, and the doors should be interlocking. A pass-though is not permitted between the hazardous drug buffer room and any unclassified area.""
1737.5(c)	Mark Johnston CVS Health Also provided at Reg Hearing	Commenter indicates that a prohibition on the use on an unclassified pass-through may create risk of microbial contamination due to the additional movement throughout the ISO classified space that trigger additional requirements to perform disinfection procedures. Commenter requests the following edit: (c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. ~~A pass-through is not allowed between the C-SEC into an unclassified space.~~	Board staff have reviewed the comment and recommend changes to the proposed language, although not based solely on this comment. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and unclassified spaces in the HD environment. Board staff are offering recommended changes to the proposed text to align with building code requirements. Further, staff are recommending changes to establish a delayed implementation for installation of interlocking doors to allow two years to come into compliance. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same time, and the doors should be interlocking. A pass-though is not permitted between the hazardous drug buffer room and any unclassified area.""

1737.5(c)	Muno Bholat Providence	In some facilities, a passthrough is located between the C-SEC and the hazardous drug storeroom (which meets USP<800> requirements to be negative pressure with at least 12 air changes per hour and externally ventilated). This pass-through allows for transport of hazardous drugs (HDs), HD CSPs, and HD waste into and out of the negative pressure buffer room to minimize the spread of HD contamination. This facility design also limits the contamination of the anteroom since HDs are not transported directly through the anteroom. This in turn also minimizes contamination to the positive buffer room and other areas outside of the anteroom. There is no requirement in USP for hazardous drug storerooms to be classified rooms. USP<800> Glossary definition of pass-through: "An enclosure with interlocking doors that is positioned between two spaces for the purpose of reducing particulate transfer while moving materials from one space to another. A pass-through serving negative-pressure rooms needs to be equipped with sealed doors." This acknowledges the reduction in particulate transfer and requires sealed doors between negative-pressure rooms. The proposed language would prohibit use of a pass-through between a C-SEC and an unclassified hazardous drug storeroom even if the HD storeroom and pass-through meet the USP <800> requirements. The USP<800> requirements are devised to minimize contamination with HDs and particulate transfer into the C-SEC. Where a pass-through is between the C-SEC and HD storeroom, the negative-pressure, externally ventilated HD storeroom provides an added buffering space between the sterility of the C-SEC and the outside area even if the HD storeroom is unclassified. The pass-through itself also provides a barrier from particles making their way into the C-SEC. And being negative-pressure and externally ventilated, the HD storeroom provides limitation to the outside space from being contaminated with HDs. **Comment Continued on Next Line**	Board staff have reviewed the comment and recommend changes to the proposed language, although not based solely on this comment. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and unclassified spaces in the HD environment. Board staff are offering recommended changes to the proposed text to align with building code requirements. Further, staff are recommending changes to establish a delayed implementation for installation of interlocking doors to allow two years to come into compliance. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same time, and the doors should be interlocking. A pass-though is not permitted between the hazardous drug buffer room and any unclassified area.""

1737.5(c)	Muno Bholat Providence	**Comment Continued from Previous Line** The proposed regulation would require these facilities to transport HDs through the anteroom instead of through the pass-through. Thus the risk of contamination of the anteroom greatly increases and being positive pressure, air and contaminants from the anteroom have a greater chance of blowing out into the outside area, outside of the cleanroom suite. Facilities designed with the pass-through between the C-SEC and HD storeroom, could require construction to upgrade HVAC air-handling systems to meet ISO 7 classification for the HD storeroom. Construction may also be required to remove a passthrough or seal it off to not be used. In these cases, many steps would be needed and take time to complete – including construction, certification of the rooms, and potential relicensing. we would recommend that the Board allow for waivers to be applied if there is a subsequent delay in compliance with the new regulations when they go into effect. Recommend modifying the wording to: (c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. ~~A pass-through is not allowed between the C-SEC into an unclassified space.~~ Additional recommendation: If a pass-through is not allowed between a C-SEC into an unclassified HD storeroom, we would ask the Board for consideration to allow licensed facilities to apply for a construction waiver for this section or a delay in implementing this section. This would factor in the time delays and allow physical changes to the facilities' structure and HVAC air handling needed to comply with the law change	See above
1737.5(c)	Keck Medicine of USC Also Provided at Reg Hearing	Comment: 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 passage of this requirement will place extreme hardship on existing facilities that may have this design in current BOP-approved licensed sterile compounding pharmacies. Given extremely high cost of cleanroom construction and modifications, this requirement may lead to pharmacy closures, negatively affecting patient access to care. Recommendation: The BOP is urged to reconsider requiring this standard, or otherwise providing for a process to allow the presence in existing construction (e.g., grandfathering). For example: "(c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. A pass-through is not allowed between the C-SEC into an unclassified space in cleanrooms constructed after [insert date]."	Board staff acknowledge, that in the HD environment, removal of the use of a passthrough, changes to workflows may be necessary to achieve compliance and as such, Board staff are recommending a in implementation. Staff note that under California Code of Regulations, Title 24 hospitals will be required to meet this requirement under specified conditions. Where a hospital elects not to meet the requirements in paragraph c, the HD will move through the anteroom, which could result in an increase in staffing cost. The transporting of a completed HD via a pass-through versus walking it through an HD room may result in additional costs; however this could be addressed through changes in workflow to manage these costs. Prohibiting the use of the pass-through is necessary to preserve the compounding environment within the HD space. Board staff are offering recommended changes to the proposed text to align with building code requirements. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same time, and the doors should be interlocking. A pass-though is not permitted between the hazardous drug buffer room and any unclassified area."" The commenter indicates that prohibition on the presence of a pass-thought between an c-sec and an unclassified space is not a requirement of USP 797 or USP 800, which is true. Staff note that it IS a requirement of Title 24, CCR 1224.19.3.3.2.8 for HD environments.

1737.5(c)	UCSF	Comment: 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 per USP 800. Recommendation: Recommend align with USP 800 section 5.3.2. as this current language would prohibit the usage of pass through and add additional delay and interruption to patient care. CCR 1737.5 Facilities and Engineering Controls: (c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. ~~A pass-through is not allowed between the C-SEC into an unclassified space.~~ An existing secondary engineering control that has a pass-through that is not an interlocking device, may continue to be used if the SOPs document that two doors may not be opened at the same time. 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.	Board staff have reviewed the comment and recommend changes to the proposed language, although not based solely on this comment. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and unclassified spaces in the HD environment. Board staff are offering recommended changes to the proposed text to align with building code requirements. Further, staff are recommending changes to establish a delayed implementation for installation of interlocking doors to allow two years to come into compliance. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same time, and the doors should be interlocking. A pass-though is not permitted between the hazardous drug buffer room and any unclassified area."
1737.5(c)	Tommy Mai Huntington Health, CSHP	Rationale: USP 800 does not prohibit using a pass-through between a classified space and an unclassified space. In addition, this requirement without an exemption for previously built classified areas will put a significant burden financially and operationally on institutions that utilize a passthrough to be compliant with the new regulations. Recommendation: Revise language to remove the requirement and to align with USP 800 to read as follows: CCR 1737.5 Facilities and Engineering Controls: (c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. A pass-through is not allowed between the C-SEC into an unclassified space. A passthrough may be allowed if installed before [OAL insert effective date]. An existing secondary engineering control that has a pass-through that is not an interlocking device, may continue to be used if the SOPs document that two doors may not be opened at the same time.	Board staff have reviewed the comment and recommend changes to the proposed language, although not based solely on this comment. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and unclassified spaces in the HD environment. Board staff are offering recommended changes to the proposed text to align with building code requirements. Further, staff are recommending changes to establish a delayed implementation for installation of interlocking doors to allow two years to come into compliance. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same time, and the doors should be interlocking. A pass-though is not permitted between the hazardous drug buffer room and any unclassified area."

1737.5(c)	Rheta Silvas Kaweah Health	Recommend: an OAL effective date for the pass-through prohibition between the C-SEC into an unclassified space. Rationale: there are newly constructed or existing clean room suites at considerable costs in the state of California that incorporate this design feature as it is not prohibited by USP Chapter <800> and is not prohibited under the OSHPD Advisory Guide for Sterile Compounding Pharmacies for hospital facilities (OSHPD 1 Buildings). In a clean room suite with an ISO-7 Anteroom shared between an ISO 7 Positive Pressure Buffer Room and ISO 7 Negative Pressure Buffer Room, optimal placement of a pass-through is between the Negative Pressure Buffer room and adjacent unclassified space and/or placement between the Negative Pressure Buffer room and adjacent unclassified negative pressure hazardous drug storage room. There are contamination control benefits afforded from this design in that the design limits entry in/out of the anteroom thereby limiting the introduction of microbial contamination into the anteroom which is then introduced into the negative pressure buffer room as a result of the pressure relationship between the 2 rooms. The benefit of a pass-through between the negative pressure buffer room and adjacent unclassified negative pressure room storage room is it avoids the storage of bulk HD refrigerated and non-refrigerated inventory in the negative pressure buffer room optimizing microbial contamination control while minimizing the risk of HD exposure by better controlling material transfer.	Board staff have reviewed the comment and recommend changes to the proposed language, although not based solely on this comment. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and unclassified spaces in the HD environment. Board staff are offering recommended changes to the proposed text to align with building code requirements. Further, staff are recommending changes to establish a delayed implementation for installation of interlocking doors to allow two years to come into compliance. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same time, and the doors should be interlocking. A pass-though is not permitted between the hazardous drug buffer room and any unclassified area."
1737.5(c)	Rick Rhoads University Compounding	(c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. A pass-through is not allowed between ~~the~~ an ISO classified C-SEC for sterile compounding into an unclassified space. Reason: Nonsterile compounding areas are not ISO classified, so the last sentence should only apply to ISO classified sterile compounding areas.	Board staff have reviewed the comment and recommend a change to the proposed langauge to clarify that the language is related to HD CSPs. Staff note that the recommended being offered by staff address the recommendations offered by this commenter.
1737.5(c)	John Gray Kaiser Permanente	Kaiser Permanente performed a literature review (see Appendix A for search terms and results) to assess whether there are data to support the notion that a properly designed pass-through cannot be used between a C-SEC and unclassified space. Based on our literature review, we found no relevant peer reviewed studies; therefore, we conclude that there is no compelling evidence to support adopting this regulation. Additionally, the Board has failed to provide any concrete evidence to support the notion that a pass through between a C-SEC and unclassified space presents an unacceptable risk of contamination if the pass through is of an appropriate design. Therefore, we conclude that there is no empirical evidence that demonstrates a risk of contamination when there is a pass-through that connects that C-SEC to unclassified space when the pass-through has sealed, interlocking doors and is HEPA filtered and we recommend that this portion of the regulation be deleted. Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. ~~A pass-through is not allowed between the C-SEC into an unclassified space.~~	Board staff have reviewed the comment and recommend changes to the proposed language, although not based solely on this comment. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and unclassified spaces in the HD environment. Board staff are offering recommended changes to the proposed text to align with building code requirements. Further, staff are recommending changes to establish a delayed implementation for installation of interlocking doors to allow two years to come into compliance. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same time, and the doors should be interlocking. A pass-though is not permitted between the hazardous drug buffer room and any unclassified area."

1737.5(c)	Marie Cottman Pacific Compounding	COMMENT: Pass-through to an unclassified space is not excluded by USP 800 Glossary definition. Consider applying the same language as allowed in 1735.5 (a) to certify that the room maintains ISO 7 classification. What is the scientific basis for this regulatory restriction? Did an expert committee assembled by the CA BOP evaluate this and make a consensus statement that justifies why it is more restrictive than the expert committee of the USP? RATIONALE: A pass-through can be tested for microbial growth, just like any other surface in the controlled space. It can be certified to maintain appropriate controls with the gasketed and interlocking doors. Appropriate cleaning of the pass-through has the potential to be effective at minimizing contamination risks and certification can verify that ISO 7 classification can be maintained while the pass-through is utilized. RECOMMENDATION: Modify language. (c) Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking. ~~A pass-through is not allowed between the C-SEC into an unclassified space~~. If a pass-through connects to an unclassified space, it must be either a HEPA purge type or biannual certification shall document that the C-SEC room can continuously maintain an ISO 7 classification throughout the opening and closing of the pass-though. Specific standard operating procedures (SOPs) shall be written to address the maintenance of the ISO 7 classification.	Board staff have reviewed the comment and recommend changes to the proposed language, although not based solely on this comment. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and unclassified spaces in the HD environment. Board staff are offering recommended changes to the proposed text to align with building code requirements. Further, staff are recommending changes to establish a delayed implementation for installation of interlocking doors to allow two years to come into compliance. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same time, and the doors should be interlocking. A pass-though is not permitted between the hazardous drug buffer room and any unclassified area."
1737.5(c)	UCSD	There's no publish or agreed upon list of volatile HDs some guidance on this would be helpful. A pass through is not allowed between the SEC into an unclassified space this will have a wide ranging impact on many pharmacies and cause a large economic impact including another round of complete compounding room redesign most pharmacies have already undergone extensive remodels just to comply with USP 797 and now this would require a whole new set of potential remodels and some pharmacies may have to shut down or change their operations. In the next section there's a requirement for a very expensive hepa Purge pass through which also creates complexity in cost and redesign uh we already do extensive Environmental Testing that shows any pattern of growth so these new changes.	Board staff have reviewed the comment and recommend changes to the proposed language, although not based solely on this comment. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and unclassified spaces in the HD environment. Board staff are offering recommended changes to the proposed text to align with building code requirements. Further, staff are recommending changes to establish a delayed implementation for installation of interlocking doors to allow two years to come into compliance. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same time, and the doors should be interlocking. A pass-though is not permitted between the hazardous drug buffer room and any unclassified area."
1737.5(d)	Rick Rhoads University Compounding	~~(d) Where a pass-through door is installed or replaced in a secondary engineering Control after [OAL insert effective date] the pass-through door shall be a HEPA purge type.~~ Reason: HEPA purge type pass-throughs are typically utilized to maintain ISO classification when transferring material from unclassified to classified sterile compounding spaces. These would not be appropriate for nonsterile HD rooms (eg. HD to non-HD room) because they are not ISO classified. Also, depending on the type of purge type pass-through, it could exacerbate HD contamination of the rooms. Please consider removing.	Board staff have reviewed the comment and recommend changes to the proposed language, although not based solely on this comment. Staff note that California Code of Regulations, Title 24, prohibits a passthrough between classified and unclassified spaces in the HD environment. Board staff are offering recommended changes to the proposed text to align with building code requirements. Further, staff are recommending changes to establish a delayed implementation for installation of interlocking doors to allow two years to come into compliance. Title 24, 1224.19.3.3.2.8 Pass-throughs "If a pass-through is used between the buffer and anteroom, both doors should not be capable of being open at the same time, and the doors should be interlocking. A pass-though is not permitted between the hazardous drug buffer room and any unclassified area."

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 handling hazardous materials. Recommended Language: ~~(e) Facility 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.~~	Board staff have reviewed the language and do not recommend a change to the proposed text based on the comment. Staff note that CCR 1751.4(g) already includes reference to the CETA guidelines; however the proposed regulation text update to the current version of the guidelines. Board staff have recommending a slight change to the proposed regulation to conform with the CETA guidelines referenced.
1737.5(e)	Marie Cottman Pacific Compounding	COMMENT: Section (e) needs to be clarified that it is only applicable to sterile HD rooms as the referenced CETA guidelines are specifically for sterile, controlled environments. RATIONALE: Upon reviewing CETA Guidelines CAG-003:2022 (chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://coeta.memberclicks.net/assets/application-guides/CAG-003%20Final_Signed.pdf) And section 2.1 specifically states that it is not for non-sterile facilities. RECOMMENDATION: Clarify that 1735.5 is for sterile areas only. (e) <u>Sterile</u> Facility 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 <u>in the sterile areas</u>.	Board staff have reviewed the comment and do not recommend changes to the proposed text based solely on this comment. Staff are recommending proposed changes to this paragraph. Staff note that the requirements should not be limited to sterile compounding and pressure differentials are required by the Chapter for CNSP hazardous preparations.
1737.6	John Gray Kaiser Permanente	Commercially available HD wipe testing kits only test for a handful of HDs.24 This severely limits the usefulness of wipe testing because a Designated Person will not know whether a wipe test was negative because compounding personnel are following the facility's SOPs or because the area tested was not exposed to the specific HDs that the selected testing kit tests for. Kaiser Permanente performed a literature review (see Appendix A for search terms and results) to assess whether there are data to support the practice of routine wipe sampling for HD residue. Based on our literature review, we found 13 peer-reviewed studies that utilized wipe sampling in the context of compounded HD preparations. Of those 13 studies, six used wipe sampling to assess the effectiveness of Closed-System Transfer Devices in limiting employee exposure to HDs, five used wipe sampling as a proxy for occupational exposure to HDs, and two used wipe sampling to assess the effectiveness of pharmacy automation in limiting employee exposure to HDs. Only one study assessed healthcare worker exposure to HDs using laboratory testing; in the case of this study, employee urine samples were tested for traces of four HDs. The investigators found that none of the 398 urine samples collected had "detectable or outside-of-the-reference-population concentrations for the four drugs evaluated."25 Based on our literature review, we conclude that there is no compelling evidence to indicate that routine wipe sampling for hazardous drug residue improves employee or patient safety. Therefore, we recommend that this proposed regulation be deleted.	Board staff have reviewed the comment and recommended changes to the proposed language to address the comment received. Staff note that the Board is only requiring an SOP to describe environmental wipe sampling. Staff note that the SOP needs to provide site specific information as the SOP will define what is necessary. As an example an SOP related to environmental wipe sample would most likely be different for a hospital versus an oncology infusion pharmacy that specialized in compounding chemotherapy agents. The environmental wipe sampling provides the facility with an understanding of exposure risks in the various environments. The facility's SOPs will determine the spaces, frequency, etc. to assess for potential cross-contamination.

1737.6(a)	Marie Cottman Pacific Compounding	COMMENT: While I acknowledge that wipe sampling for HD residue is mentioned in USP 800, it is not a requirement; likely for the same rational as the explanation included the Statement of Reasons "there are currently no studies demonstrating the effectiveness of a specific number or size of wipe samples in determining levels of HD contamination." Thus, HD wipe sampling requirements that include "actionable detection" are premature and should not be required by the board. RATIONALE:. Without industry level standards or effectiveness, any HD wipe process required by the board is faulty from the start! Further, if the licensee is required to "take action" based off of a process that is clearly not validated and known to be ineffective becomes an exercise in futility and frustration! Pharmacy owners, DPs, PICs, and pharmacists are not experts in HD chemical detection, nor in effective deactivation other than what is provided by the industry experts who, admittedly, have not yet identified a specific process that provides a reproducible result to quantify/measure the level of HD contamination much less identify or define a clinical relevance if a level is detected. Further interpretation of data that is inconsistent or not well controlled due to a host of potential influencing factors (including quantity of initial contamination, light exposure, temperature, wipe material and size, sample surface, chemical degradation properties, etc.) is beyond the scope of the responsible parties' training and expertise. The Statement of Reasons assertion that "the facility must establish their specific procedures based on their business practices. While there is no standard, the facility must still perform the sampling to check for contamination and take action to clean any contaminated areas." is instructing DPs and PICs to pick a random process out of thin air and pretend that it will generate data that indicates "measurable contamination" which will then warrant an effective remediation "plan of action." **Comments Continued on Next Line**	Board staff have reviewed the comment and recommended changes to the proposed language to address the comment received. Staff note that the Board is only requiring an SOP to describe environmental wipe sampling. Staff note that the SOP needs to provide site specific information as the SOP will define what is necessary. As an example an SOP related to environmental wipe sample would most likely be different for a hospital versus an oncology infusion pharmacy that specialized in compounding chemotherapy agents. The environmental wipe sampling provides the facility with an understanding of exposure risks in the various environments. The facilities SOPs will determine the spaces, frequency, etc.
1737.6(a)	Marie Cottman Pacific Compounding	**Comments Continued from Previous Line** RECOMMENDATION: Remove the actionable levels, but retain the practice of looking for contamination. (a) The SOPs of a premises where HDs are handled shall address environmental wipe sampling for HD surface residue, its frequency, areas of testing, levels of measurable contamination, and actions when those levels are exceeded. (b) When any actionable level of contamination is found, at a minimum the following shall occur as described in the SOPs: (1) Reevaluate work practices; (2) Reevaluate the appropriateness of deactivation, decontamination, and cleaning agents; (3) Re-train personnel on deactivation, decontamination, and cleaning; and (4) Re-train personnel on donning and doffing appropriate personal protective equipment (PPE). (b) Results of the testing should be maintained including the testing wipe system used, the date of testing, record of who completed the sampling, the location of the sampling, and which HD was identified (or supposed to be identified). (c) Results of the testing will be used to educate HD compounding staff about surface contamination as described in the facilities SOPs.	see above

1737.6(a)	UCSD	Please provide more specific requirements on a minimum standard frequency and evidence based guidance.	Board staff have reviewed the comment and recommended changes to the proposed language to address the comment received. Staff note that the Board is only requiring an SOP to describe environmental wipe sampling. Staff note that the SOP needs to provide site specific information as the SOP will define what is necessary. As an example an SOP related to environmental wipe sample would most likely be different for a hospital versus an oncology infusion pharmacy that specialized in compounding chemotherapy agents. The environmental wipe sampling provides the facility with an understanding of exposure risks in the various environments. The facilities SOPs will determine the spaces, frequency, etc.
1737.6(a)	Sam Kim USC	There is no evidence or guidance provided for licensees to follow as there is no standard for acceptable limits for hazardous drug contamination. What is an acceptable level if they do test? There are no certifying agencies for wipe sample kits to use. USP has it as a should and not a requirement.	Board staff have reviewed the comment and recommended changes to the proposed language to address the comment received. Staff note that the Board is only requiring an SOP to describe environmental wipe sampling. Staff note that the SOP needs to provide site specific information as the SOP will define what is necessary. As an example an SOP related to environmental wipe sample would most likely be different for a hospital versus an oncology infusion pharmacy that specialized in compounding chemotherapy agents. The environmental wipe sampling provides the facility with an understanding of exposure risks in the various environments. The facilities SOPs will determine the spaces, frequency, etc.
1737.6(a)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP Also submitted at Reg Hearing	Rationale: • USP 800 only recommends performing environmental wipe sampling for HD surface residue routinely. • Currently, there are currently no standards for acceptable limits for HD surface contamination.1 • Requiring additional sampling would result in increased costs for testing without any concrete actionable limits. Reference 1. Connor et al. Surface wipe sampling for antineoplastic (chemotherapy) and other hazardous drug residue in healthcare settings: Methodology and recommendations. Journal of Occupational and Environmental Hygiene. Recommendations: Request the board to consider removing the section or revise language to “should” to be consistent with USP 800 Chapter based on the absence of published information on actionable limits of HD surface contamination CCR 1737.6 Environmental Quality and Control a) The SOPs of a premises where HDs are handled ~~shall~~ <u>should</u> 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 and do not recommend any changes to the proposed text. Staff note that the Board is only requiring an SOP to describe environmental wipe sampling. Staff note that the SOP needs to provide site specific information as the SOP will define what is necessary. As an example an SOP related to environmental wipe sample would most likely be different for a hospital versus an oncology infusion pharmacy that specialized in compounding chemotherapy agents. The environmental wipe sampling provides the facility with an understanding of exposure risks in the various environments. The facilities SOPs will determine the spaces, frequency, etc.

1737.6(a)	Wendy Waldman Torrance Memorial Medical Center	Rationale: 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.1 Additionally, requiring additional sampling will add an undue burden to test without any concrete actionable limits. Reference: 1.O'Connor et al. Surface wipe sampling for antineoplastic (chemotherapy) and other hazardous drug residue in healthcare settings: Methodology and recommendations. Journal of Occupational and Environmental Hygiene. Recommendations: Suggest the board consider either removing the section entirely or revising the language to use "should" to maintain consistency with USP 800 Chapter. Additionally, providing guidance on specific requirements such as action levels, frequency of testing, and actions to take when actionable levels are reached would be beneficial, considering the absence of standards in this regard. 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 and do not recommend any changes to the proposed text. Staff note that the Board is only requiring an SOP to describe environmental wipe sampling. Staff note that the SOP needs to provide site specific information as the SOP will define what is necessary. As an example an SOP related to environmental wipe sample would most likely be different for a hospital versus an oncology infusion pharmacy that specialized in compounding chemotherapy agents. The environmental wipe sampling provides the facility with an understanding of exposure risks in the various environments. The facilities SOPs will determine the spaces, frequency, etc.
1737.6(a) & (b)	Keck Medicine of USC Also Provided at Reg Hearing	Comment: Environmental quality and control utilizing wipe sampling for hazardous drug surface residue is not a mandatory requirement in USP 800. While this is a worthwhile effort that pharmacies compounding hazardous drugs should follow, there are several significant barriers that arise when this requirement is made mandatory. First, as stated in USP 800, "there are currently no studies demonstrating the effectiveness of a specific number or size of wipe samples in determining levels of HD contamination." The proposed regulation would force pharmacies to make their own arbitrary standards, without a way to confirm the effectiveness of their SOP in determining levels of HD contamination. Additionally, the proposed regulation would require pharmacies to set their own actionable contamination limits. However, per USP 800, "there is currently no standard for acceptable limits for HD surface contamination." Given the absence of widely accepted standards for actionable limits, pharmacies will be forced to make a subjective determination without relying on evidence. It is unwarranted for the BOP to put forth this requirement in the absence of clear evidence of negative staff outcomes and associated acceptable HD surface contamination levels. **Comment Continued on Next Line**	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the Board is only requiring an SOP to describe environmental wipe sampling. Staff note that the SOP needs to provide site specific information as the SOP will define what is necessary. As an example an SOP related to environmental wipe sample would most likely be different for a hospital versus an oncology infusion pharmacy that specialized in compounding chemotherapy agents. The environmental wipe sampling provides the facility with an understanding of exposure risks in the various environments. The facility's SOPs will determine the spaces, frequency, etc.

1737.6(a) & (b)	Keck Medicine of USC	**Comment Continued from Previous Line** Furthermore, per USP 800, "there are currently no certifying agencies for vendors of wipe sample kits." Accordingly, there may be a degree of variability with performance of wipe sampling kits. Detection of trace surface contamination levels would require a high degree of test sensitivity and specificity to determine that a test is accurate enough (e.g., accurate 90% of the time with low risk of false positives or negatives). Pharmacies currently do not have a way to evaluate commercial wipe sampling kits against an established certification standard or a badge of assurance. This could pose concerns with the accuracy of the entire wipe sampling program. Lastly, there is a wide variety of chemotherapeutic agents compounded in pharmacies, and there is not a wipe sample kit vendor that, to the best of our knowledge, offers sampling kits for all chemotherapeutic agents currently available for patient care. Therefore, a pharmacy attempting to comply with the new requirement and the apparent intent of the environment quality and control program, will not be successful in doing so at present. 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.	see above
1737.6(a) & (b)	Walgreens	While USP addresses the topic of wipe sampling, it specifically highlights that no supporting studies demonstrate the effectiveness of a specific number or size of wipe samples in determining the level of HD contamination. Additionally, there are currently no certifying agencies for vendors of wipe sample kits. USP also states that there is no standard for acceptable limits for HD surface contamination or standards with which to comply. The lack of standardization and guidance for these processes is problematic and should be addressed before this language is included. We suggest the board consider only requiring wipe sampling for entities that work with antineoplastic drugs. A comprehensive safe-handling program for antineoplastic drugs may utilize wipe sampling as a tool to evaluate environmental contamination, and assurances that OHSA standards are followed must always be required. Recommended language: (a) The SOPs of a premises where HDs are handled ~~shall~~ may address environmental wipe sampling for HD surface residue, its frequency, areas of testing, levels of measurable contamination, and actions when those levels are exceeded. (b) When any ~~actionable~~ measurable level of contamination is found, at a minimum the following shall occur as described in the SOPs:	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the Board is only requiring an SOP to describe environmental wipe sampling. Staff note that the SOP needs to provide site specific information as the SOP will define what is necessary. As an example an SOP related to environmental wipe sample would most likely be different for a hospital versus an oncology infusion pharmacy that specialized in compounding chemotherapy agents. The environmental wipe sampling provides the facility with an understanding of exposure risks in the various environments. The facility's SOPs will determine the spaces, frequency, etc.
1737.6(a-b)	Philip Smyth Medisca	There are no standards for contamination action levels for HD drugs. Wipe sampling is recommended in USP 800 but not required, as there is no consensus on what to do with the results.	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that the Board is only requiring an SOP to describe environmental wipe sampling. Staff note that the SOP needs to provide site specific information as the SOP will define what is necessary. As an example an SOP related to environmental wipe sample would most likely be different for a hospital versus an oncology infusion pharmacy that specialized in compounding chemotherapy agents. The environmental wipe sampling provides the facility with an understanding of exposure risks in the various environments. The facility's SOPs will determine the spaces, frequency, etc.

1737.7(b) & (c)	Narinder Singh Santa Clara Valley Healthcare (SCVH)	This requirement is above and beyond the USP 800. There is no added value of this requirement but adds burden to the end user which can lead to errors. Please remove (b) & (c) as USP 800 doesn't require.	Board staff have reviewed the comment and recommend changes to the proposed regulation language. Staff note that the type of gloves to be used and a minimin threshold for changing gloves is established in the Chapter. Staff note that proposed changes to the text will remove the requirement to change gloves every 30 minutes.
1737.7(b) & (c)	Walgreens	Walgreens requests clarity on what defines "different". 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. Recommended language: (c) Outer gloves used for HD compounding shall be changed between each different HD API preparation.	Board staff have reviewed the comment and do not recommend a change to the proposed language. The language as drafted provides flexibility to the compounding personnel to only change the gloves between different HD preparations. This is necessary to prevent cross-contamination between different active ingredients.
1737.7(c)	Melanie Horn Sutter Health Also Provided at Reg Hearing	The Board has proposed in 1735 USP 795 language to allow for outer gloves used for HD compounding "shall be wiped between each different HD preparation." to reduce cross contamination. Changing gloves more frequently for cross contamination of HD residue levies a significant operational burden on the licensed technicians compounding HDs and the organization as a requirement. This standard has not been in place or utilized prior to this proposal no evidence has demonstrated that current HD handling practices which require routine wiping and changing of outer gloves at least every 30 minutes offers additional safety protections. The standard also is not the only mitigated protection for workers from residues during HD compounding procedures and should be assessed collectively with those additional protections to allow a decontamination process. This operational requirement requires an HD technician to change gloves up to 30 times in an average volume facility with regular HD compounding during an 8-hour shift. This restricts ability to provide patient care with no evidence of benefit. (c) Outer gloves used for HD compounding shall be wiped to decontaminate or changed between each different HD preparation.	Board staff have reviewed the comment and recommend changes to the proposed regulation language. Staff note that the type of gloves to be used and a minimin threshold for changing gloves is established in the Chapter. Staff note that proposed changes to the text will remove the requirement to change gloves every 30 minutes. Staff is unaware of any research that supports wiping gloves as a means to decontaminate. Staff notes that the Chapter specifies the types of gloves to be used.
1737.7(c)	Tommy Mai Huntington Health	Rationale: 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%).1 Reference 1. Simon N, Vasseur M, Pinturaud M, et al. Effectiveness of a Closed-System Transfer Device in Reducing Surface Contamination in a New Antineoplastic Drug-Compounding Unit: A Prospective, Controlled, Parallel Study. Ahmad A, ed. PLoS One 2016;11:e0159052. Available at: https://dx.plos.org/10.1371/journal.pone.0159052. 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 cited research demonstrates, while the CSTD does REDUCE the risk of contamination, it does not eliminate it.

1737.7(c)	Marie Cottman Pacific Compounding	COMMENT: This is a very wasteful process overall, but incredibly expensive in the clean room setting that may increase the risk of issues with gloving in the sterile C-PEC. Differentiating between a clean room setting and the nonsterile setting is recommended. RATIONALE: When HD compounding in the non-sterile space with powders and creams, though it is wasteful, changing gloves between each preparation is acceptable to prevent cross-contamination. There are no CSTDs that are available to prevent exposure to HD powders when compounding. However, in the sterile environment, there are CSTDs that minimize pressure issues, leaks, and accidental exposures very significantly! Changing gloves in the ISO-5 space takes a few minutes and generates an outer plastic wrap, an inner paper wrap, and 2 gloves each time. A sterile HD compounder may be making upwards of 5-10 compounds per hour… you can envision the waste and expense. RECOMMENDATION: modify text to differentiate non-sterile and sterile HD gloving practices. (c) Outer gloves used for nonsterile HD compounding shall be changed between each different HD preparation. Outer gloves used for sterile HD compounding shall be changed in compliance with 1737.7 (b).	Board staff have reviewed the comment and do not recommend a change to the proposed text based solely on this comment. As the cited research demonstrates, while the CSTD does REDUCE the risk of contamination, it does not eliminate it. Board staff note that the proposed regulation text only require use of sterile gloves when the compounding involved sterile preparations.
1737.7(c)	Rita Shane Cedars-Sinai	Rationale: USP 800 recommends chemotherapy gloves should be changed every 30minutes unless otherwise recommended by the manufacturer's documentation and must be changed when torn, punctured, or contaminated. 1737.7 (b) states: The outer pair of gloves that meets the ASTM D-6978 standard chemotherapy gloves shall be changed every 30 minutes during HD compounding. Requiring additional glove changes between each HD preparation adds significant burden to the workload of sterile compounding staff which could increase the risk of causing an error in compounding. Recommendations: Consider removing 1737.7 (c) requirement	Board staff have reviewed the comment and recommend changes to the proposed regulation language. Staff note that the type of gloves to be used and a minimin threshold for changing gloves is established in the Chapter. Staff note that proposed changes to the text will remove the requirement to change gloves every 30 minutes.
1737.7(c)	Jasmine Parker Pacific Compounding	COMMENT: Regarding sterile compounding, this process is costly and wasteful of gloves, and gives more opportunities for possible contamination of the hood during each re-gloving. When compounding using CSTDs, there is expected to be no leakage, exposure, or contamination from the drug products, and as such, is not expected to soil outer gloves. RECOMMENDATION: Outer gloves used for sterile HD compounding shall be changed in compliance with 1737. 7 (b).	Board staff have reviewed the comment and recommend a change to the proposed text. As the cited research demonstrates, while the CSTD does REDUCE the risk of contamination, it does not eliminate it. It is necessary to change outer gloves to avoid cross-contamination.

1737.7(c)	Wendy Waldman Torrance Memorial Medical Center	Rationale: 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%).1 Reference 1.Simon N, Vasseur M, Pinturaud M, et al. Effectiveness of a Closed-System Transfer Device in Reducing Surface Contamination in a New Antineoplastic Drug-Compounding Unit: A Prospective, Controlled, Parallel Study. Ahmad A, ed. PLoS One 2016;11:e0159052. Available at: https://dx.plos.org/10.1371/journal.pone.0159052. 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 based solely on this comment. As the cited research demonstrates, while the CSTD does REDUCE the risk of contamination, it does not eliminate it. Staff note that proposed changes to the text will remove the requirement to change gloves every 30 minutes.
1737.7(c)	CSHP	Rationale: The proposed rule requiring outer glove changes every 30 minutes during HD compounding appears arbitrary and not based on scientific evidence. While it is intended to protect staff and patients, it is unclear how this will be achieved since chemical permeation tests shows that some drugs permeate the glove in less than 30 minutes while most drugs takes longer. The rule will be closer aligned with its author's intents if it allows compounding staff and facilities to determine via SOP's the frequency of glove exchanges based on the drugs compounded. Additionally, many health-system pharmacies 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%).1 Reference 1. Simon N, Vasseur M, Pinturaud M, et al. Effectiveness of a Closed-System Transfer Device in Reducing Surface Contamination in a New Antineoplastic Drug-Compounding Unit: A Prospective, Controlled, Parallel Study. Ahmad A, ed. PLoS One 2016;11:e0159052. Available at: https://dx.plos.org/10.1371/journal.pone.0159052. Recommendations: Revise the proposed language to: b) The outer pair of gloves that meets the ASTM D-6978 standard chemotherapy gloves shall be changed ~~every 30 minutes~~ on a frequency determined by SOPs during HD compounding unless otherwise 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. (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 based solely on this comment. As the cited research demonstrates, while the CSTD does REDUCE the risk of contamination, it does not eliminate it. Staff note that proposed changes to the text will remove the requirement to change gloves every 30 minutes.

1737.7(c)	John Gray Kaiser Permanente Also Provided at Reg Hearing	Kaiser Permanente performed a literature review (see Appendix A for search terms and results) to assess whether there are data to support the practice of changing the outer glove between each different HD preparation. Based on our literature review, we found one study that mentioned the practice of changing gloves during HD compounding. However, this study only assessed compounding employee perceptions of HD exposure and referenced 30-minute interval between glove changes as the standard.27 The study did not assess the impact of more frequent glove changes (e.g. between different HD preparations) on cross contamination with HD residue. Therefore, we conclude that there is no compelling evidence to indicate that changing the outer chemotherapy gloves more frequently than the USP 800 Chapter recommends improves employee or patient safety. Additionally, the Board has failed to provide any concrete evidence that changing the outer chemotherapy gloves every 30 minutes or when torn, punctured, or contaminated, as recommended in the USP 800 Chapter, leads to an increased risk of 'cross contamination.' In attempting to establish this requirement, the Board also fails to recognize that many pharmacies routinely use Closed System Drug-Transfer Devices (CSTDs), which have been proven to prevent contamination with HD residues and vapors.28 This requirement will also significantly increase supply costs for organizations. We conservatively estimate that this requirement will increase Kaiser Permanente's supply cost by $1.5 million per year. Because the proposed regulation will increase costs to organizations with no established benefits, we encourage the Board to remove the requirement to change outer gloves between each different HD preparation.	Board staff have reviewed the comment and do not recommend a change to the proposed text based solely on this comment. As the cited research demonstrates, while the CSTD does REDUCE the risk of contamination, it does not eliminate it. Staff note that proposed changes to the text will remove the requirement to change gloves every 30 minutes. ASHP guidance notes that many studies show that areas where HDs are handled have significant surface contamination and promotes that outer gloves be removed before labeling or removing the preparation from the C-PEC.
1737.7 (d)	National Community Pharmacists Association (NCPA)	As written, this assumes that there is only a positive pressure anteroom which would require the PPE to be removed in the C-SEC. Some facilities have a negative pressure anteroom where the PPE could be removed so that it does not have to be removed in the negative pressure buffer room. These facilities with a negative pressure anteroom also have a positive pressure gowning room..	Board staff have reviewed the comment and agree that additional clarification of the proposed regulation language is appropriate; however not based solely on this comment.
1737.7(d)	Walgreens	To reduce confusion in this proposed rule, we ask the board to update the language as suggested. Recommended language: (d) PPE removal process shall be done in a manner ~~removed~~ to avoid transferring contamination to skin, the environment, and other surfaces. PPE worn during compounding shall be disposed of in the proper waste container before leaving the C-SEC. SOPs shall detail the donning and doffing of PPE and where it takes place in the C-SEC.	Board staff have reviewed the comment and agree that additional clarification of the proposed regulation language is appropriate.
1737.7(d)	Jasmine Parker Pacific Compounding	COMMENT: Removing garb in the sterile C-SEC (buffer room) will increase the risk of contaminating the C-SEC with particulates from the compounder. RECOMMENDATION: Add language to clarify difference between non sterile and sterile area donning and doffing procedures including the specific situation.	Board staff have reviewed the comment and do not recommend a change based solely on the comment. Staff note that typically the outer layer of PPE, which is potentially contaminated PPE, is removed in the negative pressure environment.

1737.7(d)	Marie Cottman Pacific Compounding	COMMENT: No issue with this in the non-sterile C-SEC, but removing garb in the sterile C-SEC (buffer room) will increase the risk of contaminating the C-SEC with human skin and hair! Differentiate between non sterile and sterile area PPE processes. RATIONALE: USP 797 states in section 3.3 "When preparing Category 2 or Category 3 CSPs, all garb should be donned in a classified area before entering the buffer room." Further, USP 797 section 4.1.2 "Typically, personnel hand hygiene and garbing procedures, staging of components, and other activities that potentially generate higher levels of particulates are performed in the anteroom." There is a specific situation outlined in USP 797 Section 5.3.2 where an HD sterile compounding area may be entered through a non-HD buffer room, special consideration is required to prevent contamination of the non-HD buffer area. RECOMMENDATION: Add language to clarify difference between non sterile and sterile area donning and doffing procedures including the specific situation in Section 5.3.2. (d)(1) In non sterile HD compounding areas, PPE shall be removed to avoid transferring contamination to skin, the environment, and other surfaces. PPE worn during compounding shall be disposed of in the proper waste container before leaving the C-SEC. SOPs shall detail the donning and doffing of PPE and where it takes place in the C-SEC. (d)(2) In sterile HD compounding areas with an anteroom connected directly to an HD C-SEC, PPE shall be removed in the anteroom to minimize particulate generating activities in the C-SEC. PPE worn during HD compounding shall be disposed of in the proper waste container before leaving the HD anteroom. SOPs shall detail the donning and doffing of PPE. (d)(3) If the negative-pressure HD buffer room is entered through the positive-pressure non-HD buffer room, a line of demarcation must be defined within the negative-pressure buffer room for donning and doffing PPE.PPE must be removed to avoid transferring contamination to skin, the environment, and other surfaces. PPE worn during compounding shall be disposed of in the proper waste container before leaving the HD C-SEC. SOPs shall detail the donning and doffing of PPE and where it takes place in the HD C-SEC.	Board staff have reviewed the comment and do not recommend a change to the proposed text based solely on the comment. Staff note that the Chapter does not draw a distinction between HD CNSPs and CSP. Staff believe the proposed regulation text offered by the commenter would be contrary to the Chapter requirements. Staff are recommending changes to the proposed text to provide further clarification of the requirement.
1737.7(d)	Scott Brunner Alliance for Pharmacy Compounding	As written, this assumes that there is only a positive pressure anteroom which would require the PPE to be removed in the C- SEC. Some facilities have a negative pressure anteroom where the PPE could be removed so that it does not have to be removed in the negative pressure buffer room. These facilities with a negative pressure anteroom also have a positive pressure gowning room.	Board staff have reviewed the comment and do not recommend a change based solely on the comment. Staff note that typically the outer layer of PPE, which is potentially contaminated PPE, is removed in the negative pressure environment.
1737.7(d)	Rheta Silvas Kaweah Health	Recommend: include the word “outer” before the second instance of the word PPE. Rationale: If PPE is doffed before leaving the C-SEC, personnel would then be on the clean side of the ante-room wearing no garb.	Board staff have reviewed the comment and do not recommend a change based solely on the comment. Staff note that typically the outer layer of PPE, which is potentially contaminated PPE, is removed in the negative pressure environment.
1737.8	Melanie Horn Sutter Health	In the Initial Statement of Reasons, states “in addition to the requirements of Title 8, California Code of Regulations, Division 1,” and the designated person “must develop the [Hazard Communication] program because the designated person “maintains the operations of the facility.” The Board’s assessment does not account for state (8 CCR 5194) and federal (29 CFR 1910.1200) hazard communication program requirements already in place at healthcare facilities. The USP 800 Chapter is written in to provide multi-disciplinary approach to the design and implementation of the hazard communication program. Recommend removing this requirement from current language.	Board staff have reviewed the commment and do not recommend a change to the proposed language. Staff are offering recommended language to provide clarify on the Board's expectations. Staff note that compliance with California Code of Regulations, Title 8 will be required.

1737.8	John Gray Kaiser Permanente	The Board's assessment fails to recognize that many facilities are fortunate to employ Environmental Health and Safety (EH&S) professionals who have specialized knowledge, skills, and experience in implementing hazard communication programs. While we believe it is reasonable for the designated person to collaborate with EH&S professionals to ensure that the hazard communication program will meet the needs of the pharmacy, it is not reasonable to expect the designated person to be solely responsible for developing and implementing the program when other expert resources are available. The Board also fails to recognize that the one paragraph proposed in this section of the regulation pales in scope to both state (8 CCR 5194) and federal regulations (29 CFR 1910.1200) and will add nothing to the rigor of the hazard communication programs are already required to be in place healthcare facilities. Additionally, the USP 800 Chapter includes rigorous requirements that all facilities, regardless of whether they employ an EH&S professional, are required to meet. However, unlike the Board's proposed regulation, which would make the designated person solely responsible for the facility's hazard communication program, the USP 800 Chapter is written in such a way that facilities that are fortunate enough to have an EH&S professional can leverage that individual's expertise to design and implement the hazard communication program. Given these factors, we recommend that this proposed regulation be deleted.	Board staff have reviewed the commment and do not recommend a change to the proposed language. Staff are offering recommended language to provide clarify on the Board's expectations. Staff note that compliance with California Code of Regulations, Title 8 will be required.
1737.9 (b)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	As noted in other areas of compounding, failing one area of training may not mean that a person should be removed from handling of HDs entirely. The supervising pharmacist needs discretion to determine if the area failed should cause complete removal of the individual.	Board staff have reviewed the comment and recommend a change to the proposed language to allow for a 14-day period for the supervising pharmacist to continue while undergoing new competency assessment.

1737.9(b)	Marie Cottman Pacific Compounding	COMMENT: I agree that a compounder who fails a competency for [dosage form A] should not continue to make [dosage form A] and should receive additional training to pass competency measures. And remediation is required by both USP 795 Section 14, paragraph 2 and USP 797 Section 20, paragraph 2. But the way proposed 1737.9 (b) is written, personnel will be removed from ALL HD handling (not just dosage form A and maybe not just compounding) when an issue is identified. This section is overly restrictive! RATIONALE: Compounding training is multifaceted and complex! Many training programs start with core skills training and then build from there. If a new compounder struggles and fails on Dosage Form C, that does not necessarily mean that they will have issues with Dosage form A. (the training needs to assess for this, though) Removing personnel from ALL HD handling until the identified deficiency is resolved may take days or weeks, depending on the issue. This will impair the facilities' ability to provide compounds in a timely manner and delay access to compounded medications to the patients of California. This proposed regulation may also force Pharmacy owners (who are willing to stay in the compounding business) to hire additional staff, for the "just in case" situation where personnel is removed from workflow for a specific failed competency; this will also raise prices for patients and continue to impede access. Further, if this regulation passes, it will encourage DPs to do only minimal assessments of staff to meet the letter of the law because it will be too costly (dollars, stress, patient dissatisfaction) to remove personnel from the daily operations. Lastly, In USP 795, section 14, paragraph 2, the USP clearly requires that the DP create a policy to address "Personnel training, competency assessments, and qualification records including corrective actions for any failures." RECOMMENDATION: Allow USP 795 Section 14, paragraph 2 USP Section 20, paragraph 2.to stand as is and delete Section 1737.9 (b). If that will not satisfy, then please reword 1737.9 (b) to: (b) All personnel responsible for handling HDs who fail any aspect of training in handling HDs shall continue to perform the failed HD competency or other dependent competencies ~~not handle HDs~~ until after successfully passing reevaluations in the deficient area(s), as detailed in the facility's SOPs.	Board staff have reviewed the comment and recommend a change to the proposed language to allow for a 14-day period for the supervising pharmacist to continue while undergoing new competency assessment.
1737.10.	Melanie Horn Sutter Health	Apply language to reference licensed supplier, distributors or wholesaler requirement since the receipt of HD APIs and antineoplastic HDs is out of the licensed pharmacy receiving control. To consider removing the entire section or clarify if receipt outside is handled (i.e. treated as a spill) or wording to allow pharmacies how to manage receipt of HD drugs such as current spill SOPs . All HD APIs and antineoplastic HDs shall be ~~shipped and~~ received from the supplier contained in segregated impervious plastic and labeled "Hazardous Drugs" on the outside of the delivery container. If not, the receiving procedure must follow the SOPs to manage a hazardous spill.	Board staff have reviewed comment and recommend a change to the proposed regulation to clarify that the requirement applies to the distributor, not the receiving pharmacy.
1737.10.	Wendy Waldman Torrance Memorial Medical Center	Rationale: Health-systems typically do not have control over how hazardous drug active pharmaceutical ingredients (HD APIs) and antineoplastic hazardous drugs (HDs) are shipped, as this process is directly managed by the distributing companies. Recommendations: Consider removing the entire section.	Board staff have reviewed comment and recommend a change to the proposed regulation to clarify that the requirement applies to the distributor, not the receiving pharmacy.

1737.10.	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	Rationale: Pharmacies/health-systems cannot control how HD APIs and antineoplastic HDs are shipped and is directly controlled by the distributing companies. Pharmacies/health-system have SOP's for receiving, handling and storage of HD medications including PPE requirements and assessment of damage or breakage. Recommendations: Consider removing this section.	Board staff have reviewed comment and recommend a change to the proposed regulation to clarify that the requirement applies to the distributor, not the receiving pharmacy.
1737.10.	Keck Medicine of USC	Comment: It is unclear if this section refers to internal shipments of hazardous drugs which a pharmacy may make, or if this standard applies to the process of receiving hazardous drugs purchased from wholesalers. If the latter, then pharmacies do not have authority over wholesalers beyond a contractual relationship with purchasing medications, and this standard would place the burden of compliance on the pharmacy, rather than the supplier. If the intent is the former, then we would recommend clarifying the statement. Recommendation: Make the following clarification, as below: "In addition to the standards in USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article. When the pharmacy ships HD APIs and antineoplastic HDs to another pharmacy or location, the HD APIs and HDs shall be shipped in segregated impervious plastic and labeled "Hazardous Drugs" on the outside of the delivery container."	Board staff have reviewed comment and recommend a change to the proposed regulation to clarify that the requirement applies to the distributor, not the receiving pharmacy.
1737.10.	UCSF	Comment: This section appears to imply that all HD (reproductive, non-antineoplastic hazardous drugs) needs to be segregated by the wholesaler. Per USP, each organization is responsible for creating their own hazardous drug list based on risk assessment and it would be challenging for wholesaler to have this aligned with each individual organization unless the Board publish a standardized list. Recommendations: recommend modified language below 1737.10. ~~Receiving~~. Shipping and Handling All HD APIs and antineoplastic HDs shall be shipped and received from the supplier in segregated impervious plastic and labeled "Hazardous Drugs" on the outside of the delivery container. Pharmacy shall develop facility SOP for appropriate handling and receiving procedure per USP.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that the Chapter refers to this section as "Receiving" similar to the proposed regulation text.
1737.10.	Walgreens	Pharmacies do not have control over how products are shipped therefore this proposed language is overreaching and should be removed and included in language for the manufacturers. We recommend removing this article. Recommended language: ~~In addition to the standards in USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article. All HD APIs and antineoplastic HDs shall be shipped and received from the supplier in segregated impervious plastic and labeled "Hazardous Drugs" on the outside of the delivery container.~~	Board staff have reviewed comment and recommend a change to the proposed regulation to clarify that the requirement applies to the distributor, not the receiving pharmacy.

1737.10.	Marie Cottman Pacific Compounding	COMMENT: The pharmacy receiving the HD API or chemo just does not have control over how the HDs are shipped by the supplier and thus no control over how they are received! The pharmacy does have control over how HDs are shipped out. You can make a separate regulation for the wholesalers that they too have to comply with these processes. RATIONALE: Common sense? We can only control what we do, not what others do… RECOMMENDATION: modify this proposed regulation: 1737.10 All HD APIs and antineoplastic HDs shall be shipped ~~and received from the supplier in segregated~~ or transported in separate impervious plastic and labeled "Hazardous Drugs" or "Chemotherapy" the outside of the delivery container. 1737.10 (a) As soon as an HD API or antineoplastic is identified during receiving, personnel will comply with SOPs for receiving HDs, including facility SOPs that address how to contain HDs to prevent accidental exposure.	Board staff have reviewed comment and recommend a change to the proposed regulation to clarify that the requirement applies to the distributor, not the receiving pharmacy.
1737.10.	John Gray Kaiser Permanente	The Board fails to recognize that pharmacies have no control over the manner in which their upstream suppliers ship hazardous drugs. Based on the text of the proposed regulation, if a pharmacist received a tote with unknown contents that contained a hazardous drug, they would be in violation of the regulation through no fault of their own. This stance is unreasonable. If the Board believes it is necessary to establish a requirement to ship hazardous drugs in the manner described in the proposed regulation, then the Board should initiate a rulemaking to add such a requirement to 16 CCR 1783 (Manufacturer, Wholesaler, or Third-Party Logistics Provider Furnishing Drugs and Devices). Recommend striking the section.	Board staff have reviewed comment and recommend a change to the proposed regulation to clarify that the requirement applies to the distributor, not the receiving pharmacy.
1737.11(a)	Marie Cottman Pacific Compounding	COMMENT: Proposed 1737.11 (a) is merely restating 4076 and 1707.5. It does not clarify, specify, or protect public safety more than the original language. RATIONALE: This proposed 1737.11 (a) is not even clarifying USP 800. RECOMMENDATION: Remove, it is redundant.	Board staff have reviewed the comment and recommend a change to the proposed regulation text not based solely on this comment. Language recommended by staff would establish a more explicit exemption for a HD that is administered as specified.
1737.11(a)	Tommy Mai Huntington Health, CSHP	Rationale: Currently, a health facility, as defined in Section 1250 of the Health and Safety Codes, are exempt from patient centered label requirements. Recommendations: To be consistent with current regulations, recommend adding exemption language to the current proposed language for HSC 1250 (a) licensed facilities as the administration of compounded medications to patients are done by health care personnel authorized to administer medications and not dispensed for outpatient use. CCR 1737.9 Labeling subsection (a): (a) Any compounded HD preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5 (i) 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 recommend a change to the proposed regulation text not based solely on this comment. Language recommended by staff would establish a more explicit exemption for a HD that is administered as specified.

1737.11(a)	Rheta Silvas Kaweah Health	Recommend: revise proposed language as follows – The prescription container of any compounded HD preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5. Rationale: adding the proposed language could imply that the prescription container labeling requirements outlined in B&PC 4076 and 1707.5 are applicable to compounded HD preparations furnished by the hospital pharmacy for administration to a patient.	Board staff have reviewed the comment and recommend a change to the proposed regulation text not based solely on this comment. Language recommended by staff would establish a more explicit exemption for a HD that is administered as specified.
1737.11(a)	Wendy Waldman Torrance Memorial Medical Center	Rationale: At present, health facilities, as outlined in Section 1250 of the Health and Safety Codes, are exempt from patient-centered label requirements. Recommendations: To align with existing regulations, it is recommended to include exemption language in the proposed language for HSC 1250 (a) licensed facilities. This is because compounded medications administered to patients are handled by healthcare personnel authorized to administer medications and are not dispensed for outpatient use. CCR 1737.9 Labeling subsection (a): Any compounded HD preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5 (i) 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 recommend a change to the proposed regulation text not based solely on this comment. Language recommended by staff would establish a more explicit exemption for a HD that is administered as specified.
1737.11(b)	Marie Cottman Pacific Compounding	COMMENT: Proposed 1737.11(b) appears to be the same as 1737.10 with a minor change in wording "shipped" rather than "transported." For brevity, combine into one sentence. RATIONALE: 1737.10 "All HD APIs and antineoplastic HDs shall be shipped and received from the supplier in segregated impervious plastic and labeled "Hazardous Drugs" on the outside of the delivery container." 1737.11(b) All HD APIs and antineoplastic HDs shall be transported from the facility in an impervious plastic container and labeled as HD on the outside of the container. RECOMMENDATION: All HD APIs and antineoplastic HDs shall be ~~shipped or~~ transported from the facility in an impervious plastic container and labeled as HD on the outside of the container.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that the language in the proposed regulation is different than the language cited by the commenter.
1737.11(b)	Walgreens	We ask for clarity on this language, does the ointment jar or capsule vial meet this requirement, or does the board intend to require the dispensing container be in a second, impervious plastic container? Recommended language: (b) All HD APIs and antineoplastic HDs shall be packaged and transported from the facility in an impervious plastic container and labeled as HD on the outside of the container.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation. Staff note that the Chapter appears to address the packaging requirements sufficiently.

1737.13	Walgreens	The requirement to utilize a plastic-backed preparation mat goes above and beyond USP standards. Many compounding entities already utilize a surface that is smooth, impervious, and non-shedding so they can be cleaned, disinfected, and decontaminated appropriately. Introducing additional materials or tools into the compounding environment also increases the risk of contamination and microorganisms. UPS <800> has specific cleaning directions that make this requirement superfluous. USP also states that you "should", not must, use a mat, and if implemented it may drive the cost of filling these compounded products up significantly. Recommended language: In addition to the standards in USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article. (a) A disposable preparation mat ~~shall~~ may 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.	Board staff have reviewed the comment and recommend a change to the proposed text to adddress the comment as well as other comments received regarding this paragraph. As proposed to be amended by staff, the proposed text would clarify that, when a mat is used. it must be changed after each different HD preparation is compounded. This is necessary to prevent cross-contamination. Further, staff note that the proposed text to adddress the comment as well as other comments received regarding this paragraph including concerns and cost implications of using preparation mats.
1737.13	Rheta Silvas Kaweah Health	Recommend: revised the proposed language to read "a disposable preparation mat shall be placed on the work surface of the C-PEC when compounding HD preparations without the use of a closed system transfer device or when use of a closed system transfer device is not possible as is the case when withdrawing an HD from an ampule. Recommend to clarify "after each drug" (may be missing a word or two?). Rationale: Requiring the use of a disposable preparation pad does introduce more opportunity for microbial contamination, increases supply and labor costs (costs associated with material transfer and terminal cleaning of supplies and the resources to do the work) and if the prep pad is too large, may interfere with airflow to the front or back air grilles of the BSC. Because a pad may absorb small spills, it could be a source of HD contamination for anything placed on it.	Board staff have reviewed the comment and recommend a change to the proposed text to adddress the comment as well as other comments received regarding this paragraph. As proposed to be amended by staff, the proposed text would clarify that, when a mat is used. it must be changed after each different HD preparation is compounded. This is necessary to prevent cross-contamination. Further, staff note that the proposed text to adddress the comment as well as other comments received regarding this paragraph including concerns and cost implications of using preparation mats.

1737.13	John Gray Kaiser Permanente Also Provided at Reg Hearing	Kaiser Permanente performed a literature review (see Appendix A for search terms and results) to assess whether there are data to support the practice of changing the disposable preparation mat after each HD is prepared. Based on our literature review, the selected search terms yielded one study; however, it was not related to the use of preparation mats during HD compounding. Therefore, we conclude that there is no compelling evidence to indicate that changing the disposable preparation mat before compounding a different HD preparation reduces the risk or cross contamination or ensures the sterility of the compounding environment. Additionally, the Board has failed to provide any concrete evidence that changing the preparation mat in the event of a spill and regularly during use, as recommended in the USP 800 Chapter, leads to an increased risk of 'cross contamination' or threatens the sterility of the compounding environment. In attempting to establish this requirement, the Board also fails to recognize that many pharmacies routinely use CSTDs, which have been proven to prevent contamination with HD residues and vapors.32 This requirement will also significantly increase supply costs for organizations. We conservatively estimate that this requirement will increase Kaiser Permanente's supply cost by $3 million per year. Because the proposed regulation will increase costs to organizations with no established benefits, we encourage the Board to remove the requirement to change the disposable preparation mat after each HD drug preparation. The word "handled" is ambiguous. At its most conservative, the proposed 1737.13(b) could be applied to prohibit batch compounding of HDs, as defined in the USP 797 Chapter, because multiple HD preparations would be handled in the C-PEC during the same discrete batch compounding process. Additionally, some HDs (e.g. Abraxane) require a long time to go into solution. It would be unreasonable if the proposed regulation were applied such that compounding personnel could not work on compounding another preparation while waiting for the drug to dissolve. Given the ambiguous nature of the proposed regulation and the operational challenges that ambiguity would create, we suggest removing this provision from the regulation.	Board staff have reviewed the comment and recommend a change to the proposed text to adddress the comment as well as other comments received regarding this paragraph. As proposed to be amended by staff, the proposed text would clarify that, when a mat is used. it must be changed after each different HD preparation is compounded. This is necessary to prevent cross-contamination. Further, staff note that the proposed text to adddress the comment as well as other comments received regarding this paragraph including concerns and cost implications of using preparation mats.
1737.13(a)	Marie Cottman Pacific Compounding	COMMENT: There is no definition of a "spill" in USP 800, nor in the proposed regs. RATIONALE: Without a definition of "spill," compliance becomes subjective. If a staticy powder is on the prep mat and not in the weight boat, is that a spill? Is it only a "spill" when it reaches a certain weight, volume, or surface area? Objective conditions for compliance cannot be established to meet the rigidity of the "shall" terms of this regulation. RECOMMENDATION: Define what constitutes an HD spill; until then let USP 800 Section 13, paragraph 4 stand as "should."	Board staff have reviewed the comment and do not recommend a change to the proposed text based solely on the comment. A pharmacist using professional judgement can determine if a spill as occurred. Staff note that if a facility chooses do so it, it can further define "spill" in the facility's SOPs.

1737.13(a)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP Also provided at Reg Hearing	Rationale: USP 800 language states that a plastic-backed preparation mat should be placed on the work surfaces of the C-PEC. The mat should be changed immediately if a spill occurs and regularly during use and should be discarded at the end of the daily compounding activity. This will result in additional process steps that could increase risk of errors and organizations will incur additional costs for replace mat after each HD prep. Additionally, CSTDs are used during compounding HD drugs to prevent spills and enhance worker protection. Revise language to be consistent with USP 800 requirements. Recommendations: Revise language to be consistent with USP 800 requirements: (a) A disposable preparation mat ~~shall~~ should be placed on the work surface of the CPEC 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,~~ during decontamination between different HD, and at the end of daily compounding activity.	Board staff have reviewed the comment and recommend a change to the proposed text to adddress the comment as well as other comments received regarding this paragraph. As proposed to be amended by staff, the proposed text would clarify that, when a mat is used. it must be changed after each different HD preparation is compounded. This is necessary to prevent cross-contamination. Further, staff note that the proposed text to adddress the comment as well as other comments received regarding this paragraph including concerns and cost implications of using preparation mats.
1737.13(a)	Melanie Horn Sutter Health	USP 800 language states that a preparation mat should be placed on the work surfaces of the C-PEC. The mat should be changed immediately if a spill occurs and regularly during use and should be discarded at the end of the daily compounding activity. Additionally, CSTDs are used when compounding HD drugs to prevent spills and enhance worker protection. If the regulation required for preparation mats be used when compounding HD drugs, this halts HD compounding in the event of a shortage of this item. Sterile mats are extremely costly to replace between each HD prep and do not facilitate routine sanitization of the DCA nor a process of performing DDCD between each HD prep. The mats within the PEC while closed should not be a requirement to perform sterile HD compounding with the other USP 800 required protections in place. This as a standard introduces significant and costly waste without identified benefit to mandate usage. Mats may be used in the event of a spill of for other purposes but must not be mandated to provide compounding inside a BSC. Recommendations: Revise language to be consistent with USP 800 requirements but require if/when a mat is used it is sterile and replaced routinely. (a) A disposable preparation mat shall be placed on the work surface of the C-PEC when compounding sterile 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,~~ regularly during use, and at the end of daily compounding activity.	Board staff have reviewed the comment and recommend a change to the proposed text to adddress the comment as well as other comments received regarding this paragraph. As proposed to be amended by staff, the proposed text would clarify that, when a mat is used. it must be changed after each different HD preparation is compounded. This is necessary to prevent cross-contamination. Further, staff note that the proposed text to adddress the comment as well as other comments received regarding this paragraph including concerns and cost implications of using preparation mats.

1737.13(a)	Wendy Waldman Torrance Memorial Medical Center	Rationale: According to USP 800, a plastic-backed preparation mat is recommended to be placed on the work surfaces of the C-PEC. This mat should be changed immediately in case of a spill and regularly during use, and it should be discarded at the end of daily compounding activity. Additionally, Closed System Transfer Devices (CSTDs) are utilized during the compounding of hazardous drugs (HD) to prevent spills and enhance worker protection. Requiring preparation mats for HD compounding could pose a patient safety concern in the event of a shortage, as institutions may be unable to compound HD drugs for patients. Recommendations: Revise language to be consistent with USP 800 requirements: (a) A disposable preparation mat ~~shall~~ should be placed on the work surface of the CPEC 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~~, during decontamination between different HD, and at the end of daily compounding activity.	Board staff have reviewed the comment and recommend a change to the proposed text to adddress the comment as well as other comments received regarding this paragraph. As proposed to be amended by staff, the proposed text would clarify that, when a mat is used. it must be changed after each different HD preparation is compounded. This is necessary to prevent cross-contamination. Further, staff note that the proposed text to adddress the comment as well as other comments received regarding this paragraph including concerns and cost implications of using preparation mats.
1737.13(a)	Keck Medicine of USC	Comment: This requirement would create unnecessary risk for contamination and potentially bacterial growth thereby negatively affecting patient care. The preparation mats have the theoretical benefit of containing possible spills. HD spills are now extremely uncommon given that USP 800 mandates the use of closed-system transfer devices for compounding antineoplastic drugs. On the other hand, the mats are associated with risks that may outweigh this theoretical benefit. The mat, even if itself sterile, presents an additional unnecessary element in the PEC that may promote bacterial growth by not allowing the surface underneath the mat to dry thoroughly. The process of frequent exchanges of the mat (required to be changed after each HD drug in this section) may promote unwarranted ingress and egress of material and thereby increase contamination – the mats are not completely lint-free, but rather, low-lint. In addition to increasing the risk of contamination while providing minimal, if any, added benefit for protecting compounding personnel, the cost of the sterile mats would place undue burden on compounding pharmacies. For instance, one popular vendor of healthcare products makes such sterile chemotherapy preparation mats available at a cost of $695 for a case of 100. Taking only a single pharmacy within our health-system, the annualized financial impact of this subjective regulation would amount to -$291,900, not including tax. **Comment Continues on Next Line**	Board staff have reviewed the comment and recommend a change to the proposed text to adddress the comment as well as other comments received regarding this paragraph. As proposed to be amended by staff, the proposed text would clarify that, when a mat is used. it must be changed after each different HD preparation is compounded. This is necessary to prevent cross-contamination. Further, staff note that the proposed text to adddress the comment as well as other comments received regarding this paragraph including concerns and cost implications of using preparation mats.

1737.13(a)	Keck Medicine of USC	**Comment Continued from Previous Line** To our knowledge, the pharmacy profession has been moving away from using prep mats over the past decade. Our health-system pharmacies have not used HD mats for many years without any spill incidents, positive employee satisfaction, and pristine surface sampling results. In our view, making the use of HD preparation a requirement will be a backwards step for patient safety and healthcare efficiency. Recommendation: Make the use of the preparation mats optional, and if used, then facilities shall follow the outlined steps. Recommend re-writing the section as follows: "(a) A disposable preparation mat may be placed on the work surface of the C-PEC when compounding HD preparations. Where the compounding is a sterile preparation and a preparation mat is used, the mat shall be sterile. If used, the preparation mat shall be changed immediately if a spill occurs, after each HD drug, and at the end of daily compounding activity."	see above
1737.13(a)	Rick Rhoads University Compounding Also provided at Reg Hearing	(a) A disposable preparation mat shall be placed on the work surface of the C-PEC when compounding antineoplastic HD preparations. For non-antineoplastic HD preparations, an assessment of risk may be performed for alternative work practices. 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. Reason: This is would greatly impact the work practices of compounders, and may not be beneficial for all dosage forms and hazard types. Please consider either removing or requiring for antineoplastic HDs only. Mats could be considered in an assessment of risk for all other hazard types (which is utilized in USP <800>).	Board staff have reviewed the comment and recommend a change to the proposed text to adddress the comment as well as other comments received regarding this paragraph. As proposed to be amended by staff, the proposed text would clarify that, when a mat is used. it must be changed after each different HD preparation is compounded. This is necessary to prevent cross-contamination. Further, staff note that the proposed text to adddress the comment as well as other comments received regarding this paragraph including concerns and cost implications of using preparation mats.
1737.13(a)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	Change "the mat must be sterile" to "the mat must be cleaned with germicidal cleaner and then sanitized with sterile 70% IPA prior to use."	Board staff have reviewed the comment and recommend a change to the proposed text to adddress the comment as well as other comments received regarding this paragraph. As proposed to be amended by staff, the proposed text would clarify that, when a mat is used. it must be changed after each different HD preparation is compounded. This is necessary to prevent cross-contamination. Further, staff note that the proposed text to adddress the comment as well as other comments received regarding this paragraph including concerns and cost implications of using preparation mats. Board staff is not aware of a cleanable mat that can be used inside a hood that meets the requirements of the Chapter.
1737.13(b)	Marie Cottman Pacific Compounding	COMMENT: A variety of products may take significant time to reconstitute (15 to 30 min). RATIONALE: It's reasonable to prepare multiple, same type, closed preparations at the same time to enable efficient operations, provided the space is organized so compounding errors do not occur. It is not necessary to specify, in regulation, this level of compounding activity specificity. This should fall to the professional judgment of the licensees (RPhs and DPs). RECOMMENDATION: (b) Only one type of HD preparation may be handled in a C-PEC at one time.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Board staff note that the proposed regulation text as noticed provides flexibility to allow for mulitple units of the same HD preparation to be prepared at one time.

1737.13(b)	Jasmine Parker Pacific Compounding	COMMENT: There are products that take significant time to reconstitute (15 to 30 min) and if there is only one available hood to work in, this severely hinders the ability of a facility to service multiple orders at once. RECOMMENDATION: (b) Only one HD preparation may be handled in a C-PEC at one time.	Board staff have reviewed the comment and do not recommend a change to the proposed text. Board staff note that the proposed regulation text as noticed provides flexibility to allow for mulitple units of the same HD preparation to be prepared at one time.
1737.14(a)	Walgreens	We again ask for clarity on this language, does the ointment jar or capsule vial meet this requirement? Or does the board intend to have the dispensing container must be in a second, impervious plastic container? Is the same materials used for shipping the products from the manufacturer to the store sufficient?	Board staff have reviewed the comment and recommend a change to the proposed text to address the comment. Staff Board note that the CDC's NIOSH has references available in this area that may assist in the development of an SOP where the facility determines such an approach is approrpriate. References: Managing Hazardous Drug Exposures: Information for Healthcare Settings: https://www.cdc.gov/niosh/docs/2023-130/2023-130.pdf?id=10.26616/NIOSHPUB2023130 . Board staff are recommending a change to the proposed text in CCR Section 1737.14(a) based on other comments received.
1737.14(a)(1)	Marie Cottman Pacific Compounding	COMMENT: There is no definition of a "decontaminated impervious plastic container." What is the definition of decontaminated? What constitutes a plastic container? A pliable 2 mil baggie? A stiff 6mil baggie? Hard plastic? Double bag? Would a new container have to be decontaminated, too? RATIONALE: Without definition of what a decontaminated impervious plastic container is, compliance cannot be determined by a PIC. RECOMMENDATION: (a) When dispensing an HD to a patient or patient's agent for administration, the pharmacy shall: (1) Place the HD in a ~~decontaminated impervious plastic container~~ container suitable for hazardous items to prevent HD exposure, with an HD label on the outside of the container;	Board staff have reviewed the comment and recommend a change to the proposed text, although not based solely on this comment. Staff Board note that the CDC's NIOSH has references available in this area that may assist in the development of an SOP where the facility determines such an approach is appropriate. References: Managing Hazardous Drug Exposures: Information for Healthcare Settings: https://www.cdc.gov/niosh/docs/2023-130/2023-130.pdf?id=10.26616/NIOSHPUB2023130. Board staff are recommending a change to the proposed text in CCR Section 1737.14(a) based on other comments received.
1737.14(a)(2)	Marie Cottman Pacific Compounding	COMMENT: This proposed regulation is overly restrictive. Not all antineoplastic HDs are infused. Some are injected IM, others IV push, and some administered as ophthalmic injections or drops. RATIONALE: Not all antineoplastic HDs are prepared for infusion and thus compliance with this regulation will be impossible unless limited to infusions. Additionally, there may be situations where an infusion bag should not be spiked prior to transport to prevent leakage in transport. Nursing procedures exist at facilities where antineoplastic infusions are administered for antineoplastic HD bag spiking and handling. RECOMMENDATION: (2) For an antineoplastic HD infusion, attach tubing if appropriate and prime ~~all~~ tubing if appropriate and attach a CSTD when appropriate.	Board staff have reviewed the comment and recommend a change to the proposed text to address the comment.
1737.14(a)(2)	National Community Pharmacists Association (NCPA)	Not all lines can be primed in the pharmacy. Medications hung as a secondary that are already primed may mess up the entire setup of the lines.	Board staff have reviewed the comment and recommend a change to the proposed text, although not based solely on this comment.

1737.14(a)(2)	Jasmine Parker Pacific Compounding	COMMENT: Not all antineoplastic HDs are infused. Some are injected IM, others IV push, and some administered as ophthalmic injections or drops. RECOMMENDATION: (2) For an antineoplastic HD infusions, attach and prime tubing if appropriate and attach a CSTD when appropriate.	Board staff have reviewed the comment and recommend a change to the proposed text to address the comment.
1737.14(b)	Tommy Mai Huntington Health, CSHP	Rationale: 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. Recommendations: Recommend adding exemption language to the current proposed language for HSC 1250 (a) licensed facilities as the administration of compounded medications to patients are done by health care personnel trained and authorized to administer HD medications and not dispensed for outpatient use. (i) 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 recommend a proposed change to the regulation text to clarify that the requirement applies when an HD is dispensed to the patient or patient's agent.
1737.14(b)	Walgreens	Mandating the supply of gloves for antineoplastic HD compounded products is overreaching. However, we do feel that the dispensing pharmacy and the administering facility should ensure that the appropriate gloves are available for administration. Proposed language: (b) When furnishing an antineoplastic HD, the dispensing pharmacy must ensure a sufficient supply of gloves that meet the ASTM D-6978 standard to allow for appropriate administration, handling, and disposal of HD drugs by the patient or the patient's agent is available ~~shall be provided~~.	Board staff have reviewed the comment and recommend a proposed change to the regulation text to clarify that the requirement applies when an HD is dispensed to the patient or patient's agent.
1737.14(b)	Lauren Honda Valor Compounding Also Submitted in Reg Hearning	Having been a designated person, I greatly appreciate The Board's concern for patient education and safety surrounding hazardous drug handling. Guidelines for administering hazardous drugs have generally applied to in-patient settings. As written, the proposed language would extend to hazardous compounded prescriptions dispensed to the patient or patient's agent in an outpatient setting. If that is the intention of The Board, then compounding pharmacies dispensing hazardous compounded medications would benefit from an example written by The Board to define what a sufficient supply of gloves would be.	Board staff have reviewed the comment and do not recomment a change to the proposed regulation text based on the comment. Staff note that a pharmacist, using professional judgment, should determine the number of gloves required for use by the patient or patient's agent. Based on separate comments received related to the proposed text in CCR Section 1737.14(b), staff are recommending changes to the proposed text.

1737.14(b)	Wendy Waldman Torrance Memorial Medical Center	Rationale: 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. Recommendations: Suggest including exemption language for HSC 1250 (a) licensed facilities. This exemption would account for the fact that compounded medications are administered to patients by healthcare personnel who are trained and authorized to handle hazardous drug (HD) medications, and these medications are not dispensed for outpatient use. (i) 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 recommend a proposed change to the regulation text to clarify that the requirement applies when an HD is dispensed to the patient or patient's agent.
1737.14(b)	Melanie Horn Sutter Health	To avoid confusion about the cases in which gloves must be provided to the patient or patient's agent, recommend clarifying the regulation to indicate that this requirement applies only to situations in which the HD is supplied to the patient or patient's agent.	Board staff have reviewed the comment and recommend a proposed change to the regulation text to clarify that the requirement applies when an HD is dispensed to the patient or patient's agent.
1737.14(b)	Jasmine Parker Pacific Compounding	COMMENT: If not furnishing the drug directly to the patient (ex. Going to a facility or other provider to adm sinister), they should provide their own gloves. RECOMMENDATION: (b) When furnishing an antineoplastic HD, a sufficient supply of gloves that meet the ASTM D-6978 standard to allow for appropriate administration, handling, and disposal of HD drugs by the patient or the patient's agent shall be provided. should be made available, when needed.	Board staff have reviewed the comment and recommend a proposed change to the regulation text to clarify that the requirement applies when an HD is dispensed to the patient or patient's agent.
1737.14(b)	National Community Pharmacists Association (NCPA), Scott Brunner Alliance for Pharmacy Compounding	Who bears liability if the patient refuses to pay for the gloves? Who bears liability if the patient does not use the gloves that shall be made available for purchase?	Board staff have review the comment and do not recommend a change to the proposed text based on the comment. The comments appear broad in nature and ask questions beyond the scope of the proposed regulation. Board staff note that staff are recommending changes to the proposed text in response to other comments received about this section.
1737.14(b)	John Gray Kaiser Permanente	When furnishing an antineoplastic HD to the patient or patient's agent, a sufficient supply of gloves that meet the ASTM D-6978 standard to allow for appropriate administration, handling, and disposal of HD drugs by the patient or the patient's agent shall be provided. To avoid confusion about the cases in which gloves must be provided to the patient or patient's agent, we recommend clarifying the regulation to indicate that this requirement applies only to situations in which the HD is supplied to the patient or patient's agent.	Board staff have reviewed the comment and recommend a proposed change to the regulation text to clarify that the requirement applies when an HD is dispened to the patient or patient's agent.

1737.14(b)	Marie Cottman Pacific Compounding	COMMENT: Not every dispense situation requires provision of gloves. Changing the language to allow PIC discretion is appropriate. RATIONALE: There are many instances where a sterile HD is furnished to a provider (e.g. clinic, pharmacy, infusion nurse) who has their own internal procedures for handling, gowning, gloving, and disposal of administration supplies. The items provided by the compounding pharmacy may not be known or congruent with those procedures. Also, not all patients want to get their administration supplies from the compounding pharmacy, depending on item preference, cost, and insurance coverage. Also, as written, it could be inferred that the "shall be provided" is done at no cost to the patient. RECOMMENDATION: (b) When furnishing an antineoplastic HD, a sufficient supply of gloves that meet the ASTM D-6978 standard to allow for appropriate administration, handling, and disposal of HD drugs by the patient or the patient's agent ~~shall be provided.~~ should be made available, when needed	Board staff have reviewed the comment and recommend a proposed change to the regulation text to clarify that the requirement applies when an HD is dispensed to the patient or patient's agent.
1737.15(b)	Marie Cottman Pacific Compounding	COMMENT: This overly restricts the ability to purchase and use products as provided by manufacturers. RATIONALE: USP 800 specifies that solutions should not be applied by wipes, not solutions sprayed onto the surface being cleaned, as the spray could spread HD contaminants. There is no logic to the prevention of using a sprayer bottle to saturate a clean wiper, then using that wiper on the surface being cleaned. It is also reasonable to argue that using a sprayer to apply a solution onto a wiper provides more even coverage over a palm-sized area than pouring solution onto a single spot on the wiper, which also risks spillage over and possible slipping hazards from the less controlled pouring of the cleaning solution and it not being fully absorbed by the wipe. RECOMMENDATION: (b) Agents used for deactivation, decontamination, cleaning, and disinfecting all areas and equipment involved in HD handling shall be applied through the use of wipes wetted with the appropriate solution and shall not be applied or delivered to the ~~wipe~~ surface by use of a spray bottle to avoid spreading HD residue.	Board staff have reviewed the comment and recommend a change to the proposed text in response to the comment. Staff note that the Chapter specifies that the appropriate solution is not delivered by a spray bottle to avoid spreading HD residue.
1737.15(b)	Jasmine Parker Pacific Compounding	COMMENT: This working is overly limiting of how a chemical shall be applied. What if i'm pouring from the spray bottle and not spraying it? Several companies sell their products packaged in sprayer bottles, however, we do not use the nozzle and instead wet the wipe by pouring. RECOMMENDATION: (b) Agents used for deactivation, decontamination, cleaning, and disinfecting all areas and equipment involved in HD handling shall be applied through the use of wipes wetted with the appropriate solution and shall not be applied or delivered to a surface by spraying to avoid spreading HD residue.	Board staff have reviewed the comment and recommend a change to the proposed text not based solely on this comment. Staff note that the Chapter specifies that the appropriate solution is not delivered by a spray bottle to avoid spreading HD residue.

1737.15(c)	Walgreens	The designated person of the organization should have the authority to approve the SOPs. Recommended language: (c) SOPs shall include procedures for deactivation and decontamination of the HD preparation container closure and shall be approved by the designated person, pharmacist-in-charge or professional director of a clinic, as applicable.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text based on this comment. Staff note that based on other comments received, staff recomment that the proposed regulation text in CCR 1737.15(c) be removed. Staff remind the commenter that BPC 4113 provide that the pharmacist-in-charge is responsible for a pharmacy's complaince with all state and federal laws and regulations pertaining to to the practice of pharmacy, including the requirements established in these regulations.
1737.15(c)	Marie Cottman Pacific Compounding	COMMENT: This proposed regulation suggests completing decontamination of a finished CSP closure system which would include applying deactivation/decontamination solution(s) to the IV bag, ports, and attached tubing. This is completely impractical and there is no information about the compatibility of IV bag and tubing sets to not absorb the decontamination solutions required to complete such a task. RATIONALE: USP 800 states that there is no single deactivator for all HDs, but the goal is “complete surface decontamination.” 800 also references the EPA-registered oxidizers, but the EPA search engine does not have any results for this term. Studies, in fact, have shown some chemotherapy agents become more cytotoxic after being treated with oxidizers, so even though the original chemical was not detected, the new chemical entity formed by the “deactivation” process was more cancerous. Since there is no definition of “deactivation” nor a list of EPA products that have approved labeling to be effective at “deactivating” a drug, nor is there an ability for a PIC to determine if they are compliant with “deactivation” regulatory requirements, the language should not be in the regulations. Additionally, wiping down HD CSPs, after they have been compounded, is not a standard of practice and potentially exposes the patient to unknown hazards with no scientific basis showing that CSP containers have contaminations that need to be addressed. RECOMMENDATION: Remove as we cannot verify compatibility nor guarantee that the deactivation/decontamination products don't CAUSE harm to patients.	Board staff have reviewed the comment and based on the comment received, believe the proposed regulation text in CCR 1737.15(c) should be removed from the proposed regulation text.
1737.16	Marie Cottman Pacific Compounding	Rationale: As required by USP 800, personnel are trained to handle HD, which includes cleaning up an HD spill, prior to handling HD. In large and multi-hospital health-systems, maintaining a list of all qualified personnel to attend an HD spill would be difficult. Recommendations: Recommend the following revision to the proposed regulation: ~~The premises shall maintain a list of properly trained and qualified personnel able to clean up an HD spill.~~ An SOP shall outline how such a qualified person to clean up an HD spill will be always available while HDs are handled.	Board staff have reviewed the comment and recommend a change to the proposed text that ensures an entities SOP outlines how a qualified person will be available at all times.

1737.16	Walgreens	Spill cleaning should be included in required policies, procedures, and training at pharmacies that handle HD products. We feel that there should be assurances that the individuals who may participate in HD spill clean-up are appropriately trained, however, a separate list of the trained and qualified personnel is not always necessary. Recommended language: Unless all pharmacy staff are trained in HD spill control, the premises shall maintain a list of properly trained and qualified personnel able to clean up an HD spill. An SOP shall outline how such a qualified person will be available at all times while HDs are handled.	Board staff have reviewed the comment and recommend a change to the proposed text that ensures an entities SOP outlines how a qualified person will be available at all times.
1737.16	Melanie Horn Sutter Health	As required by USP 800, personnel are trained to handle HD, which includes cleaning up an HD spill, prior to handling HD. The proposed language implies all spills are manageable by trained personnel; however, SOPS outline overall spill management including the determination of need to have spill response beyond internal individuals such as a major spill incident. Recommend modification to align with requirements of spill control plan. ~~The premises shall maintain a list of properly trained and qualified personnel able to clean up an HD spill.~~ An SOP shall outline spill management plan and procedures and qualifications for spill management. ~~such a qualified person to clean up an HD spill will be always available while HDs are handled.~~	Board staff have reviewed the comment and recommend a change to the proposed text that ensures an entity's SOP outlines how a qualified person will be available at all times.
1737.16	Wendy Waldman Torrance Memorial Medical Center	Rationale: In compliance with USP 800, personnel undergo training to handle hazardous drugs (HDs), which encompasses the procedure for cleaning up an HD spill before handling HDs. In healthcare today there are constant staff changes; maintaining an up-to-date list of all qualified personnel to attend an HD spill would be difficult. Recommendations: Recommend the following revision to the following proposed regulation: ~~The premises shall maintain a list of properly trained and qualified personnel able to clean up an HD spill.~~ An SOP shall outline how such a qualified person to clean up an HD spill will be always available while HDs are handled.	Board staff have reviewed the comment and recommend a change to the proposed text that ensures an entities SOP outlines how a qualified person will be available at all times.
1737.16	Mark Johnston CVS Health Also provided at Reg Hearing	Commenter believes that maintaining employee lists, which may be subject to frequent change, is an example of a burden that APhA, ASHP, and NABP has asked the Board not to promulgate. We believe that spill control can be adequately handled within the framework of the SOP mandated by proposed 1737.17(b)(15). Therefore, we request the striking of proposed 1737.16 in its entirety. ~~1737.16. Spill Control. In addition to the standards in USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article. The premises shall maintain a list of properly trained and qualified personnel able to clean up an HD spill. An SOP shall outline how such a qualified person will be available at all times while HDs are handled.~~	Board staff have reviewed the comment and recommend a change to the proposed text that ensures an entities SOP outlines how a qualified person will be available at all times.

1737.16	John Gray Kaiser Permanente	The ~~premises~~ designated person shall maintain a list of properly trained and qualified personnel able to clean up an HD spill. An SOP shall outline how such a qualified person will be available at all times while HDs are handled. A premises is a building, and a building is not able to maintain a list; therefore, we recommend amending the regulation by changing the term “premises” to “designated person”.	Board staff have reviewed the comment and recommend a change to the proposed text that ensures an entities SOP outlines how a qualified person will be available at all times.
1737.17(a)	John Gray Kaiser Permanente	The designated person for ~~A~~any ~~premises~~ pharmacy engaged in the compounding or handling of HDs shall maintain and follow written SOPs. A premises is a building, and a building is not able to maintain a list; therefore, we recommend amending the regulation by changing the term “premises” to “designated person”.	Staff have reviewed the comment and recommend a change to the proposed language not based solely on this comment to align the proposed regulation text with the language used in the Chapter.
1737.17(b)(3)	Mark Johnston CVS Health	Commenter states 1737.17(b)(3) requires the SOP to address “designation of HD areas”; however, USP 800 does not require separate areas when only dispensing manufactured dosage forms. Commenter requests the following edit: (3) Designation of HD areas or separate counting trays/spatulas	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that such a change would be contrary to the Chapter. Staff note that the SOPs are necessary for anyone handling HDs to avoid cross-contamination and ensure the appropriate environmental conditions.
1737.17(b)(5)	Mark Johnston CVS Health	Commenter states 1737.17(5) also requires the SOP to address “storage”, but again, USP 800 does not require special storage for manufacturer’s bottles. Commenter requests the following edit: (5) Storage for HD removed from manufacturer’s packaging	Board staff have reviewed the comment and do not recommend a change to the proposed text. Staff note that such a change would be contrary to the Chapter. Staff note that the SOPs are necessary for anyone handling HDs to avoid cross-contamination and ensure the appropriate environmental conditions.