Title 16. Board of Pharmacy
Fourth Modified Text

Proposed changes to the current regulation language are shown by ~~strikethrough~~ for deleted language and underline for added language.

Modifications to the proposed regulation language are shown by ~~double strikethrough~~ for deleted language and double underline for added language.

The second modified regulation text is indicated with a ~~**bold double strikethrough**~~ for deletions and a **bold wavy underline** for additions.

The third modified regulation text is indicated with a yellow highlighted ~~**bold double strikethough with dotted underline**~~ for deletions and a yellow highlighted **bold dotted underline** for additions.

The fourth modified regulation text is indicated with a bright green highlighted ~~***bold italics double strikethrough***~~ for deletions and a bright green highlighted ***bold italics*** for additions.

Amend title of Article 4.5 and Repeal sections 1735 through1735.8 of Article 4.5, adopt new titles and sections 1735 through 1735.14 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 4.5 Nonsterile Compounding ~~in Pharmacies~~

1735. Compounding Definitions.

In addition to the definitions contained in United States Pharmacopeia (USP) General Chapter 795 titled *Pharmaceutical Compounding – Nonsterile Preparations* (USP Chapter 795), the following definitions apply to this article and supplement the definitions provided in USP Chapter 795 for compounded nonsterile preparations (CNSPs).

(a) "Approved labeling" means the Food and Drug Administration's (FDA) approved labeling in accordance with sections 201.56 and 201.57 of title 21, Code of Federal Regulations that includes FDA approved information (as applicable) for the diluent, the resultant strength, the container closure system, and storage time.

(b) Designated person(s) means one or more individuals assigned by the pharmacist-in-charge **(PIC)** to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of the

compounded nonsterile preparations ("CNSP") for the purposes of this article). Nothing in this definition allows for a designated person to exceed the scope of their issued license. When the designated person is not a pharmacist, the **Pharmacist-in-Charge** (PIC) must review all practices related to the operations of the facility that require the professional judgment of a pharmacist. **Nothing in this definition prohibits the PIC from also serving as the designated person.**

(c) "Diluent" means a liquid with no pharmacological activity used in reconstitution, such as ***pP**urified **wW**ater* or ***sS**terile **wW**ater*.

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

(e) "Integrity" means retention of strength until the beyond use date provided on the label when the preparation is stored and handled according to the label directions.

(f) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, or the absence of active ingredients other than those listed on the label, or the absence of inactive ingredients other than those listed on the master formulation record as specified in USP Chapter 795.

(g) "Repackaging" means the act of removing a product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation of the product or preparation, when the act is not done pursuant to a prescription.

(h) "Strength" means the amount of active ingredient per unit of a compounded drug preparation.

Note: Authority cited: Sections 4005, and 4126.8 of Business and Professions Code. Reference: Sections 4005, 4076, 4081, 4126.8, 4169, 4301 and 4332 of the Business and Professions Code.

1735.1. Introduction and Scope.

In addition to the standards in ~~the~~ USP Chapter 795 and~~,~~ **section 503a (21 U.S.C. §353a) of the Federal** Food, Drug, **and** Cosmetic Act (FDCA) ~~**section 503a (21 U.S.C. §353a)**~~ the compounding of a CNSP shall meet the following requirements of this article.

(a) Nonsterile compounding is performed by or under the direct supervision and control of a licensed pharmacist pursuant to a patient specific prescription, unless otherwise specified in this article.

~~(b) Repackaging of a conventionally manufactured drug product is not considered compounding if compliant with USP Chapter 1178, *Good Repackaging Practices.*~~

~~(c)~~ (b) Reconstitution of a conventionally manufactured drug product that is not done in accordance with the FDA approved directions is considered compounding.

~~(d)~~ (c) Notwithstanding subdivision (a), a limited quantity of a CNSP may be prepared and stored in advance of receipt of a patient specific prescription document where **it is necessary**, and solely in such quantity~~, **as is necessary,**~~ to ensure continuity of care of individual patients based on a documented history of prescriptions for those patient populations.

~~(e)~~ (d) A reasonable quantity of a compounded drug preparation may be furnished to a veterinary office for use by the veterinarian that is sufficient:

(1) for administration or application to veterinary patients solely in the veterinarian's office

(2) for furnishing of no~~t~~ more than ~~**7-day supply, or up to no more than a**~~14~~.~~ days ~~**supply for antibiotics**~~, for an individual patient~~,~~ as fairly estimated by the prescriber, and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing for an individual patient.

~~(f)~~ (e) In addition to prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that:

(1) Is essentially a copy of one or more commercially available drug products, unless:

(A) the drug product appears in an American Society of Health-System Pharmacists (ASHP) **Drug Shortages List** or FDA Drug Shortages Database **of drugs** that are in short supply at the time of compounding or **within 60 days of the end of the shortage ~~and at the time of dispensing~~**, or **in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained, or**

(B) The pharmacist ~~**determines**~~ **verifies** and documents that the compounding produces a clinically significant difference for the medical need of an identified individual patient~~, as determined by~~:

~~(i) the prescribing practitioner,~~

~~(ii) the compounding pharmacist, and~~

~~(iii) the dispensing pharmacist(s).~~

(C) Documentation describing the conditions in (1)(A) ~~&~~ **and** (1)(B) is maintained in a readily retrievable format.

(2) Is made with any component not suitable for use in a CNSP for the intended veterinary population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA). **When a veterinarian, acting within a valid veterinarian-client-patient relationship (VCPR), determines there is no medically appropriate human or animal drug that is FDA-approved, conditionally approved, or indexed to treat the animal, a pharmacy may use a bulk drug substance to compound an animal drug. This compound shall be in compliance with the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022.**

~~(g)~~ (f) Prior to allowing any CNSP to be compounded within a pharmacy, the pharmacist-in-charge shall complete a self-assessment consistent with the requirements established in section 1715.

~~(h)~~ (g) In addition to the provisions ~~**provided**~~ in section 1707.2, consultation **includes** ~~**shall be provided to the patient and/or patient's agent concerning**~~ proper use, storage, handling, and disposal of the CNSP and related supplies furnished.

A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge compounded medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge compounded medications ~~which~~ that meets the requirements of Business and Professions Code Section 4074.

~~(i)~~ (h) CNSPs with human whole blood or human whole blood derivatives shall be compounded ~~prepared~~ in compliance with Health and Safety Code section 1602.5.

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

Note: Authority cited: Sections 4005, and 4126.8 of Business and Professions Code. Reference: Sections 4005, 4051, 4052, 4076, 4081, 4105, 4126.8, 4169, 4301, 4306.5 and 4332 of the Business and Professions Code, and 21 U.S.C. Sections 355 and Part 530.

1735.2. Personnel Training and Evaluation.

In addition to the standards in the USP Chapter 795, **the following requirements apply to nonsterile compounding. the compounding of CNSP shall meet the following requirements of this article.**

(a) Training and competency procedures for all personnel who compound or have direct oversight supervision and control of personnel performing compounding, or verifying compounding preparations verifying, and/or handling a CNSP shall address the following topics:

(1) Quality assurance and quality control procedures,

(2) Container closure and equipment selection, and

(3) Component selection and handling.

(b) A pharmacist responsible for, or directly supervising, the compounding of CNSPs, shall demonstrate proficiency in skills necessary to ensure the integrity, strength, quality, and labeled strength of a CNSP as described in the facility's SOPs as referenced in section 1735.11.

(bc) Compounding personnel or persons with direct supervision and control oversight of over personnel performing compounding, who fail any aspect of ongoing training and evaluation related to the USP **Chapter** 795's core competencies shall not be involved in compounding of or oversight of the preparation of a CNSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs.

(cd) Any person assigned to provide the training specified in this section shall have demonstrated competency in the skills in which the person will provide training, or observe and measure competency described in the facility's SOPs as referenced in section 1735.11. Documentation must be maintained demonstrating compliance.

Note: Authority cited: Sections 4005, and 4126.8 of Business and Professions Code. Reference: Sections 4005, 4051, 4052, 4076, 4081, 4126.8, 4301, 4306.5 and 4332 of the Business and Professions Code; **section 503a (21 U.S.C. §353a),** Food Drug Cosmetic Act (FDCA) **section 503a (21 U.S.C. §353a).**

1735.3. Personnel Hygiene and Garbing.

In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding.

(a) Facilities shall require individuals entering the compounding area to report **to the supervising pharmacist** if the**y have** rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection, or any other medical condition, to determine if such condition could contaminate a CNSP or the environment per the facility's SOPs. ~~**Prior to admitting any personnel into a compounding area, the supervising pharmacist shall evaluate whether** compounding **personnel is experiencing any of the above conditions** following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection, or any other medical condition, to determine if such condition **could contaminate a CNSP or the environment** ("contaminating condition"). After such evaluation and determination, t~~**T**he supervising pharmacist shall not allow personnel with potentially contaminating conditions to enter the compounding area.

(b) A gown and face mask shall be used whenever a closed system processing device is required.

(c) Disposable garb shall not be shared by personnel ~~staff~~ and shall be discarded if soiled and after each shift. Gowns intended for reuse during the shift ~~All garb removed during a shift~~ must remain in the compounding area.

(d) Gloves shall be wiped or replaced before beginning a CNSP that contains different components.

(e) ~~Non-disposable~~Reusable garb and equipment shall be cleaned with a germicidal cleaning agent and sanitized with 70% isopropyl alcohol at least daily and before use by different personnel use ~~before re-use~~.(1) Any reuseable gowns must be laundered, per the facility's SOPs before reuse

(f) Any garbing accommodations provided by the designated person shall be documented and the record shall include the name of the individual granted the accommodation, date granted and description of the reasons for granting the accommodation. The records shall be retained in accordance with Business and Professions Code section 4081.

Note: Authority cited: Sections 4005~~,~~ and 4126.8 of Business and Professions Code. Reference: Sections 4001.1, 4005, 4081, 4126.8, 4301, 4306.5, and 4332 of the Business and Professions Code.

1735.4. Building and Facilities.

In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding.

(a) A sink used for compounding or hand hygiene shall not be part of a restroom or water closet.

(b) Purified water, distilled water, ~~or~~ reverse osmosis water, or higher quality water shall be used for rinsing equipment and utensils.

(c) No CNSP shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the law or the facility's SOPs.

Note: Authority cited: Sections 4005, and 4126.8 of Business and Professions Code. Reference: Sections 4001.1, 4005, 4126.8, 4169, and 4306.5 of the Business and Profession Code.

1735.5. Cleaning and Sanitizing

In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding.

(a) The facility's documentation of each occurrence of the cleaning and sanitizing of the compounding area shall include the identity of the person completing the cleaning and sanitizing, as well as the product name(s) of the cleaning and sanitizing agent(s) used.

(b) Any cleaning or sanitizing agents used by the facility to meet the requirements in this article shall be used in accordance with manufacturers' specifications.

Note: Authority cited: Sections 4005~~,~~ and 4126.8 of Business and Professions Code. Reference: Sections 4005, 4081, 4126.8, 4301, and 4332 of the Business and Profession**s** Code.

1735.6. Equipment and Components.

In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding.

(a) Any equipment used to compound a CNSP shall be used in accordance with the manufacturer's specifications**, where established by the manufacturer**.

(b) Any component used to compound a CNSP shall be used and stored in accordance with all federal laws and regulations and industry standards, including the manufacturers' specifications and requirements.

Note: Authority cited: Sections 4005~~,~~ and 4126.8 of Business and Professions Code. Reference: Sections 4005, 4126.8, and 4301 of the Business and Profession**s** Code.

1735.7. Master Formulation and Compounding Records.

In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding.

(a) A CNSP shall not be compounded until the facility has first prepared a written master formulation record in compliance with USP Chapter 795 and includes the following additional elements:

(1) If a source is referenced to support the assigned beyond-use date (BUD), ~~each~~ the source referenced shall be readily retrievable at the time of compounding and shall be maintained for three years from the date each CNSP is dispensed.

(2) Instructions for storage and handling of the CNSP.

(b) Where a facility does not routinely compound a particular drug preparation, the master formulation record for that preparation may be recorded on the prescription document itself.

(c) A compounding record (CR) shall be maintained and, upon request, **~~be~~** produced as a single document developed in compliance with USP Chapter 795, and includes the following additional elements:

~~(1) The date and time of compounding, which is the time when compounding the CNSP started, and which determines when the assigned BUD starts.~~

(**~~2~~1**) The manufacturer, lot number, and expiration date for each component.

(**~~3~~ 2**) The assigned internal identification number, which shall be unique for each CR.

(**~~4~~ 3**) The total quantity or amount compounded, which shall include the number of units made and the volume or weight of each unit, where applicable.

(**~~5~~ 4**) The identity of personnel ~~each person~~ performing the compounding, **~~the~~** pharmacist ~~the person~~ who has direct ~~oversight~~ supervision and control of compounding, and the pharmacist verifying the final drug preparation**, if different**.

Note: Authority cited: Sections 4005~~,~~ and 4126.8 of Business and Professions Code. Reference: Sections 4005, 4081, 4105, 4126.8, 4301 and 4332 of the Business and Profession**s** Code.

1735.8. Release Inspections and Testing.

In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding.

A pharmacist performing or supervising the nonsterile compounding and the dispensing pharmacist are ~~is~~ responsible for the integrity, strength, quality, and labeled strength of a CNSP until the beyond-use date indicated on the label ~~provided the patient or the patient's agent follows the label instructions provided on the CNSP for storage and handling after receiving the CNSP~~ so long as label instructions for storage and handling are followed after the preparation is dispensed.

Note: Authority cited: Sections 4005~~,~~ and 4126.8 of Business and Professions Code. Reference: Sections 4005, 4076, 4126.8, 4169, 4301 and 4306.5 of the Business and Profession**s** Code.

1735.9. Labeling.

In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding.

(a) A CNSP's label shall also include the following:

(1) Route of intended administration, and

(2) Name of compounding facility and name of dispensing facility (if different).

(b) A CNSP's labeling shall also include:

(1) Any special handling instructions,

(2) Any applicable warning statements, and

(3) Name, address, and phone number of the compounding facility if the CNSP is to be sent outside of the facility or healthcare system in which it was compounded.

~~**(c) The label for any**~~ ~~Any~~ ~~**CNSP 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. A CNSP that is administered to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility, or a juvenile detention facility shall be labeled with patient name, the directions for the use of the drug, and date of issuance, but is otherwise exempt from these requirements.**~~

Note: Authority cited: Sections 4005~~,~~ and 4126.8, ~~of~~ Business and Professions Code. Reference: Sections 4005, 4016, 4076, 4126.8, and 4301, ~~of the~~ Business and Profession**s** Code.

1735.10. Establishing Beyond-Use Dates.

In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding.

(a) Beyond-use dates (BUDs) assigned with only a date shall expire at 11:59 p.m. **(23:59)** on that date.

(b) A CNSP's BUD shall not exceed any of the following:

(1) The chemical and physical stability data of the active pharmaceutical ingredient (API) and any added component in the preparation,

(2) The compatibility and degradation of the container–closure system with the finished preparation (e.g., possible leaching, interactions, and storage conditions),

(3) The shortest remaining expiration date or BUD of any of the starting components, unless allowed by USP Chapter 795.

~~(c) If antimicrobial effectiveness testing results provided by a current FDA-registered drug establishment or outsourcing facility or published in current peer-reviewed literature sources are used, the reference in its entirety (including the raw data and testing method suitability) shall be readily retrievable in accordance with Business and Professions Code section 4081 for three years from the last date the CNSP was dispensed.~~

(c) When antimicrobial effectiveness is provided by a current FDA-registered drug establishment or an outsourcing facility, the testing must be USP Chapter 51, *Antimicrobial Effectiveness Testing*, compliant. If such testing is used, or if relying upon current published peer-reviewed literature sources, the reference or test in its ~~**entirely**~~ **entirety** shall be readily retrievable in accordance with Business and Professions Code section 4081 for three years from the last date the CNSP was dispensed.

Note: Authority cited: Sections 4005~~,~~ and 4126.8, ~~of~~ Business and Professions Code. Reference: Sections 4005, 4081, 4105, 4126.8, 4169, 4301, and 4332, ~~of the~~ Business and Profession**s** Code.

1735.11. Standard Operating Procedures (SOPs).

In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding.

(a) The facility's standard operating procedures (SOPs) for nonsterile compounding shall be followed and shall:

(1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding.

(2) Also describe the following:

(A) Methods by which the supervising pharmacist will ensure the quality of compounded drug preparations.

(B) If applicable, ~~P~~**p**rocedures for handling, compounding, and disposal of infectious materials. The SOPs shall also describe the facility's protocols for cleanups and spills in conformity with local health jurisdictional standards, if applicable.

(C) The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins.

~~(D) The method for complying with any other requirements specifically required to be addressed in the facility's SOPs as described in this article.~~

(**~~E~~D**) The validated processes for storage, shipping containers (as applicable) and transportation of temperature sensitive CNSPs (as applicable) to preserve quality standards for integrity, quality and labeled strength.

(**FF**) The pharmacist responsible for the review of all complaints related to a potential quality problem with a CNSP **~~and all adverse drug experiences~~** in the event the PIC is not available within 72 hours of the receipt of the complaint or occurrence.

(**~~G~~F**) Actions to be taken if the compounding area or equipment is rendered unusable or in a downtime situation.

(b) The SOPs shall be reviewed on an annual basis by the pharmacist-in-charge. Such review shall be documented by the pharmacist-in-charge consistent with the facility's SOPs. The SOPs shall be updated any time changes are made to compounding processes, the facility, or other changes occur that impact the CNSP. Such SOP changes shall be disseminated to the affected staff prior to implementation. **Documentation of compliance with the subdivision shall be maintained for three years.**

(c) Failure to follow written SOPs constitutes a basis for enforcement action.

Note: Authority cited: Sections 4005~~,~~ and 4126.8, ~~of~~ Business and Professions Code. Reference: Sections 4005, 4052, 4081, 4126.8, 4301, and 4332, ~~of the~~ Business and Profession**s** Code.

1735.12. Quality Assurance and Quality Control.

In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding.

(a) The facility's quality assurance program shall comply with section 1711 and the standards contained in USP Chapter 1163, ~~entitled~~ *Quality Assurance in Pharmaceutical Compounding*. In addition, the program shall include ~~**the following:**~~

~~**(1) A**~~ **a** written procedure for ~~**scheduled**~~ action, such as a recall, in the event any compounded drug preparation is discovered to be outside the expected standards for integrity, quality, or labeled strength.

~~**(2) A written procedure for responding to out-of-range temperature variations within the medication storage areas where a furnished drug may be returned for furnishing to another patient.**~~

(b) The Board shall be notified in writing within ~~72~~ 96 hours of the facility's receipt of a complaint of a potential quality problem ~~**or the occurrence of an adverse drug experience as defined in 21 CFR 310.305(b)**~~ ~~drug event~~ involving a CNSP.

(c) **Consistent with the facility's SOPs, a review shall be initiated** of ~~**All**~~ **any** complaints made to the facility related to a potential quality problem with a CNSP ~~**and all adverse drug experiences events shall be reviewed consistent with the facility's SOPs by the pharmacist-in-charge**~~ within 72 hours of receipt of the complaint ~~**or occurrence of the adverse drug experience**~~ ~~event~~. Such a review shall be documented and dated as defined in the SOPs.

Note: Authority cited: Sections 4005~~,~~ **and** 4126.8 of Business and Professions Code. Reference: Sections 4005, 4081, 4126.8, 4126.9, 4169, 4301 and 4332 of the Business and Profession**s** Code.

1735.13. CNSP Packaging and Transporting.

In addition to the standards set forth in USP Chapter 795, the facility shall ensure appropriate processes for storage, shipping containers and temperature sensitive CNSPs as provided for in the facility's SOPs.

Note: Authority cited: Sections 4005~~,~~ and 4126.8 of Business and Professions Code. Reference: Sections 4005, 4081, 4126.8, 4169, and 4332 of the Business and Profession**s** Code.

1735.14. Documentation.

In addition to the standards set forth in USP Chapter 795, the following requirements apply to nonsterile compounding.

(a) Records shall be maintained as required by USP Chapter 795 and this article in a readily retrievable form~~,~~ for at least three years from the date the record was created or relied upon to meet the requirements of this article. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070.

(b) Records ~~created~~ shall be created and maintained in a manner **~~to~~ that will** provide an audit trail for revisions and updates of each record document. Prior versions of each record must be maintained, for at least three years from the date the record was created**, modified,** or relied upon, in a readily retrievable format and include **~~the~~ all** changes to the document, identification of the individual who made **~~the~~ each** change, and the date of each change.

Note: Authority cited: Sections 4005~~,~~ and 4126.8 ~~of~~ Business and Professions Code. Reference: Sections 4005, 4081, 4105, 4126.8, 4301 and 4332 of the Business and Profession**s** Code.

1735.15. Flavoring Agents.

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

(1) Provisions of accommodations as described in Personnel Preparation, Section 3.1 of USP Chapter 795.

(2) Provisions for cleaning and sanitizing designated compounding area when in use.

(3) Provisions to ensure documentation is available and maintained confirming that the quality of the medication is not impacted by adding the flavoring agent.

(4) Provisions for maintaining the elements of the compounding record to ensure information is readily retrievable upon request.

(5) Provisions to ensure the prescription label includes information that a flavoring agent was added.

(6) Provisions to ensure documentation is available to support the establishment of a BUD.

(7) Provisions for reporting to the Board the facility's receipt of a complaint of a potential quality problem involving the CNSP. At a minimum the provisions shall require notification to the Board within 96 hours of receipt of a complaint.

(b) A pharmacist may compound by combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of the patient or patient's agent without consultation with the prescriber or the prescriber's authorized agent. A pharmacist performing such compounding must document the compounding ~~on~~ in the prescription or compounding record.

Repeal sections 1751-1751.12 of Article 7 and add new Article 4.6, titles and sections 1736 through 1736.21, to Article 4.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 4.6 Sterile Compounding

1736. Sterile Compounding Definitions.

The definitions in ~~in~~ this section shall be applicable to this Article and supplement the definitions provided in United States Pharmacopeia (USP) General Chapter 797 (USP Chapter 797), titled *Pharmaceutical Compounding – Sterile Preparations*~~. The following definitions apply to this article and supplement the definitions provided in USP Chapter 797.~~ for compounded sterile preparations (CSPs).

(a) "Compounding personnel" means any person involved in any procedure, activity, or ~~oversight~~ direct supervision and control of ~~the~~ preparation of CSPs~~compounding process~~.

(b) "Designated compounding area or compounding area" means a restricted location within a facility that limits **personnel** access, where only activities and items related to compounding are present.

(c) "Designated person(s)" means one or more individuals assigned by the pharmacist-in-charge (PIC) to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of the compounded sterile preparations. Nothing in this definition allows for the designated person to 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 professional judgment of a pharmacist. **Nothing in this definition prohibits the PIC from also serving as the designated person.**

(d) "Diluent" means a liquid with no pharmacological activity used in reconstitution, such as sterile water for injection.

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

(f) "Integrity" means retention of strength until the beyond use date provided on the

label, when the preparation is stored and handled according to the label directions.

(g) "Quality" means ~~the degree to which the components and preparation meets the intended specifications, complies with relevant law and regulation, and means~~ the absence of harmful levels of contaminants, including but not limited to filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, or the absence of inactive ingredients other than those listed on the master formulation record as specified in USP **Chapter** 797.

(h) "Strength" means amount of active ingredient per unit of a compounded drug preparation.

Note: Authority cited: Sections 4005, 4126.8, 4127 of Business and Professions Code. Reference: Sections 4005, 4057, 4127, 4127.1, 4301 and 4332 of the Business and Profession Code.

1736.1. Introduction and Scope.

In addition to the standards set forth in USP Chapter 797 and **section 503a (21 U.S.C. §353a) of the Federal** Food Drug Cosmetic Act (FDCA) ~~section 503a (21 U.S.C. §353a)~~ the following requirements apply throughout this article.

~~This article applies to compounded sterile preparations (CSP)s as defined in USP Chapter 797, titled *Pharmaceutical Compounding – Sterile Preparations*. In addition to the standards in the USP Chapter 797, the preparation of a CSP shall meet the following requirements of this article.~~

(a) For the purposes of this article, sterile compounding occurs, by or under the direct supervision and control of a licensed pharmacist, pursuant to a patient specific prescription, unless otherwise specified in this article.

(b) (1) Except as allowed in paragraph (2), CSPs for direct and immediate administration as provided in **~~the~~ USP** Chapter **797** shall only be compounded in those limited situations where the failure to administer such CSP could result in loss of life or intense suffering of an identifiable patient. Any such compounding shall be only in such quantity as is necessary to meet the immediate need of the patient. If not already documented in the patient's medical record, ~~D~~documentation for each such CSP shall also include ~~identification of the CSP,~~ the compounded date and time, ~~number of units compounded~~, the patient's name and patient's unique identifier and the circumstance causing the immediate need of the patient. Such documentation ~~may be available in the patient's medical record and~~ need not be redocumented by the compounding staff if already available.

(2) If the sterile compounding equipment or environment fail(s) to meet any required specification, **after attempts to remediate pursuant to the facility's SOPs are**

unsuccessful. an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may only be used for ~~24~~ **48** hours after such failure(s). All such failures must be documented in accordance with facility's SOP**.** ~~and~~ ***Failures requiring use of immediate use provisions*** shall be reported to the ~~**BOP**~~ **Board** within 72 hours ***of the transition to immediate use provisions***.

(3) If the sterile compounding equipment or environment fail(s) to meet any required specification in a critical access hospital, as defined in the Social Security Act 42 U.S.C. 1395i-4 section (c)(2)(B), after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering ~~or~~ of an identifiable patient. This provision may be used for 120 hours after such failure(s). All such failures shall be documented in accordance with facility's SOPs. ~~and~~ *Failures requiring use of immediate use provisions* shall be reported to the Board within 72 hours *of the transition to immediate use provisions*.

(c) Notwithstanding subdivision (a) a limited quantity of CSP may be prepared and stored in advance of receipt of a patient specific prescription document where, and solely in such quantity, as is necessary to ensure continuity of care for identified patients based on a documented history of prescriptions for that patient population.

(d) A reasonable quantity of a ~~compounded drug preparation~~CSP may be furnished to a veterinary office for use by the veterinarian that is sufficient:

(1) for administration or application to veterinary patients solely in the veterinarian's office;

(2) for furnishing of not more than a ~~**120-hour**~~ **7-day** supply for an individual patient, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing;

(A) With the exception of a topical ophthalmic where up to a 28-day supply may be furnished to veterinarian's office for an individual patient. Such topical ophthalmics shall be compliant with USP **Chapter** 797 section 14.5, Multiple-Dose CSPs.

(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP may be compounded that:

(1) Is essentially a copy of one or more commercially available drug products, unless:

(A) that drug product appears in an American Society of Health-System Pharmacists (ASHP) **Drug Shortages List** or FDA Drug Shortages Database **of**

drugs that are in short supply at the time of compounding and at the time of dispensing, or in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained, or

(B) The pharmacist **~~determines~~ verifies** and documents that the preparation produces a clinically significant difference based on the medical need of an identified individual patient~~, as determined by~~:

~~(i) the prescribing practitioner,~~

~~(ii) the compounding pharmacist, and~~

~~(iii) the dispensing pharmacist(s).~~

(C) Documentation describing the conditions in subsections (1)(A) & (1)(B) is maintained in a readily retrievable format.

(2) Is made with any component not suitable for use in a CSP for the intended veterinary~~patient~~ population, unless allowable under Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA). **When a veterinarian, acting within a valid veterinarian-client-patient relationship (VCPR) determines there is no medically appropriate human or animal drug that is FDA-approved, conditionally approved, or indexed to treat the animal a pharmacy may use a bulk drug substance to compound an animal drug. This compounding shall be done in compliance with the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued in August 2022.**

(3) Is made with a non-sterile component for which a conventionally manufactured sterile component is available ~~**and appropriate for the intended CSP,**~~ unless the CSP **master formula supports such use and is appropriate for the intended CSP.** ~~**is compounded in full compliance with USP 797 Category 3 requirements, or the conventionally manufactured sterile component appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database**~~.

(4) Requires end product sterilization unless sterilization occurs within the same licensed compounding location.

(f) Prior to allowing any CSP to be compounded within a pharmacy, the pharmacist-in-charge shall complete a self-assessment consistent with the requirements established in section 1715.

(g) In addition to the provisions in Section 1707.2 of this Division, consultation **includes** ~~**shall be provided to the patient and/or patient's agent concerning**~~ proper use, storage, handling and disposal of the CSP and related supplies furnished.

(1) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge compounded medications that meets the requirements of Business and Professions Code Section 4074.

(h) CSPs with human whole blood or human whole blood derivatives shall be produced in compliance with Health and Safety Code section 1602.5. **This shall not apply to the compounding of an FDA-approved human whole blood or human whole blood derivative product.**

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4123, 4126.8, 4127.1, 4127.2, Business and Professions Code, Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a).

1736.2. Personnel Training and Evaluation.

In addition to the standards set forth in USP Chapter 797, the following requirements apply to sterile compounding.

(a) Training and competency procedures for all personnel who compound or have direct ~~oversight~~supervision and control of ~~compounding~~ personnel performing compounding shall address the following topics:

(1) Quality assurance and quality control procedures,

(2) Container closure and equipment selection,

(3) Component selection and handling, and

(4) Sterilization techniques, when applicable.

(b) Initial and ongoing aseptic manipulation training and competency documentation shall include the Primary Engineering Control (PEC) type and PEC unique identifier used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and materials used in aseptic compounding. **Garbing and hand hygiene competencies and A~~a~~**septic **~~qualifications~~ manipulation competencies** from one premises may be used for another premises if all of the following conditions are met:

(1) The Standard Operating Procedures (SOPs) required by section 1736.17 related to compounding are identical.

(2) The Secondary Engineering Control (SEC) facility designs are sufficiently similar to accommodate the use of the same SOPs.

(3) The PECs are of the same type and sufficiently similar to accommodate the use of the same SOPs describing use and cleaning.

(c) Aseptic manipulation ongoing training and competency shall occur each time and for each staff member involved in an occurrence where the quality assurance program required by the SOPs yields an unacceptable result, as defined in the SOPs, that may indicate microbial contamination of CSPs due to poor practices. Aseptic manipulation ongoing training and competency procedures shall be defined in the facility's SOPs.

(d) Compounding personnel or persons with direct ~~oversight~~ supervision and control ~~over~~ of compounding personnel who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall not be involved in compounding ~~or oversight of the preparation~~ of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. A person with only direct supervision and control ~~oversight over~~of personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation may continue to provide only direct supervision and control of personnel~~,~~ ~~oversight~~ for no more than ~~14~~ 30 days after a failure of any aspect while applicable aseptic manipulation ongoing training and competency evaluation results are pending.

(e) Any person assigned to provide the training specified in this section shall have demonstrated competency in the skills in which the person will provide training or observe and measure competency described in the facility's SOPs. Documentation demonstrating compliance with training and competency must be maintained.

Note: Authority cited: Sections 4005, 4126.8, 4127 of Business and Professions Code. Reference: Sections 4005, 4127, 4301 and 4332 of the Business and Profession Code.

1736.3. Personnel Hygiene and Garbing

In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.

(a) The pharmacist with supervision and control~~overseeing~~ of compounding shall not allow personnel with potentially contaminating conditions to enter the designated compounding area.

(b) The pharmacist ~~overseeing~~ with supervision and control of compounding shall not allow personnel to enter the compounding area with visible non-removable piercings, which could increase the risk of contamination of CSP**s**.

(c) **With the exception of sterile gloves, ~~G~~g**arb shall be donned in an anteroom or immediately outside the segregated compounding area (SCA). **Sterile gloves shall be donned in a classified room or SCA.** Donning and doffing garb shall not occur in the anteroom at the same time unless the facility's SOP**s** define specific processes that must be followed to prevent contamination.

(d) Restricted access barrier system and pharmaceutical isolator sleeves and gloves shall be changed according to both the manufacturer's recommendations and the facility's SOP**s**.

(e) Any garbing accommodations provided by a designated person shall be documented and the documentation shall include the name of the individual granted the accommodation, date granted and description of the reasons for granting the accommodation. The record shall be retained in accordance with Business and Professions Code section 4081.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005~~,~~ and 4126.8, Business and Professions Code.

1736.4. Facilities and Engineering Controls

In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding**.**

(a) A sink used for compounding or hand hygiene shall not be part of a restroom or water closet.

(b) If an SCA is used:

(1) Except for walls, the SCA's visible perimeter shall be at least 1 meter from all sides of the PEC**,** or the SCA can be located in a separate room.

(2) Surfaces within the SCA shall be smooth, impervious, free from cracks and crevices, and non-shedding so they can be easily cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate.

(c)(1) Designated compounding area(s) shall typically be maintained at a temperature of 20° Celsius or cooler.

(2) The temperature shall be monitored in each room of the designated compounding area each day that compounding is performed, either manually or by a continuous recording device.

(d) Where a pass-through is installed in a secondary engineering control after [OAL insert effective date], the doors must be interlocking. 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.

~~**(e) Except as provided in subsection (d), dynamic interactions between areas and rooms with classified air and unclassified air shall be controlled through a heating, ventilation, and air condition (HVAC) system.**~~

(**f e**) No CSP shall be compounded if the compounding environment fails to meet criteria specified in law or the facility's SOPs**, unless such compounding is being performed consistent with immediate use provisions**.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005~~,~~ and 4126.8, Business and Professions Code.

1736.5 Certification and Recertification

In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.

(a) Testing and certification of all ISO classified areas shall be completed by a qualified technician knowledgeable with certification methods and procedures outlined in the Controlled Environment Testing Association**'s** (CETA)~~'s~~ Certification Guide for Sterile Compounding Facilities as specified in this section. Testing shall be performed in accordance with CETA**'s** Certification Guide for Sterile Compounding Facilities (CAG-003, Revised 2022), which is hereby incorporated by reference.

(b) CETA standard(s) used to perform certification testing in all ISO classified areas shall be recorded on the report issued by the certifying technician in accordance with the Certification Guide for Sterile Compounding Facilities.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.

1736.6 Microbiological Air and Surface Monitoring.

In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.

~~(a) At a minimum of every 6 months, air and surface sampling results shall be identified to at least the genus level, regardless of the CFU count to trend for growth of microorganisms. Investigation must be consistent with the deviation and must include evaluation of trends. If the laboratory is unable to identify to the genus level, the facility shall maintain with the sample results written documentation that no identification to that level could be made and an explanation as to why it could not.~~

~~(b)~~ Environmental sampling shall be done in compliance with **the** Controlled

Environment Testing Association's Certification Application Guide USP <797> Viable Environmental **Monitoring for Sterile Compounding Facilities** ~~**Sampling & Gowning Evaluation**~~ (CAG-009, Revised **September** ~~**October**~~ ~~2022~~ 2020), which is hereby incorporated by reference.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005~~,~~ and 4126.8, Business and Professions Code.

1736.7 Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA.

In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.

(a) Any cleaning, disinfecting, and sporicidal disinfectants used by the facility to meet the requirements in this article shall be used in accordance with manufacturers' specifications.

(b) Reusable cleaning supplies, not for use in the PEC, shall not be stored within 1 meter of the PEC.

(c) The facility's documentation of each occurrence of the cleaning, disinfecting, and applying of sporicidal disinfectants in the compounding area shall include the identity of the person completing the cleaning and disinfecting as well as the product name(s) of the cleaning, disinfecting, and sporicidal agent(s) used.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.

1736.8 Introducing Items into the SEC and PEC.

In addition to the requirements in USP Chapter 797, the following requirement applies to sterile compounding.

Introducing items into the SEC and PEC shall comply with the SOPs as required in section 1736.17.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.

1736.9 Equipment, Supplies, and Components.

In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.

(a) All equipment and supplies used to compound a CSP shall be used in accordance with manufacturers' specifications and shall be surface compatible.

(b) Incubators used by the facility shall be cleaned, maintained, calibrated, and operated in accordance with manufacturers' specifications. For incubators without specific manufacturers' specifications, cleaning shall take place at least every 30 days and calibration shall take place at least every 12 months. Temperatures must be monitored either manually or by a continuous recording device during incubation, and the results shall be reviewed and documented as described in the facility's SOPs.

(c) Any component used to compound a CSP shall be used and stored in accordance with all state and federal laws and the manufacturer's specifications and requirements.

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

~~*(e)(1)Except as provided in (2), When when a bulk drug substance or API is used to compound a CSP, it shall comply with a USP drug monograph, be the active substance of an FDA approved drug, or be listed in 21 CFR section 216, or unless authorized by a public health official in an emergency use situation for a patient-specific compounded sterile preparation.*~~

~~*(2) A bulk drug substance nominated for inclusion in 21 CFR section 216.23(a) and for which the FDA determined that the nomination included adequate information for the FDA to evaluate the substance and that the substance does not appear to present significant safety risks, and accordingly included in the published 503A Category 1 bulk drug substances list, may be used in compounding in accordance with this article if all of the following conditions are satisfied.*~~

~~*(A) Any facility using a bulk drug substance permitted by this subdivision shall:*~~

~~*(i) Assign a beyond-use date, supported by stability data obtained using stability-indicating analytical methods consistent with the provisions established in USP 797 Section 14.4.3, or stability information for a patient enrolled in a clinical trial that is approved by a U.S. Department of Health and Human Services (HHS) registered Institutional Review Board (IRB). The stability data or information is required regardless of the USP Category of CSP.*~~

~~*(ii) Dispense pursuant to a patient-specific prescription that documents the clinical circumstances that require the use of a bulk drug substance currently on the 503A Category 1 bulk drug substance list.*~~

~~*(iii 3) Failure to compound pursuant to this subdivision and the facility's SOPs constitutes unprofessional conduct and shall be deemed as posing an immediate threat to the public health as established subject to the provisions in Business and Professions Code section 4127.3*~~

(e) All APIs and other components used must be evaluated for suitability for use in sterile drug preparations, as provided in USP 797, Section 9.3 Components, and follow the USP drug monograph if one exists. Components labeled with "not for pharmaceutical use", "not for injectable use", "not for human use" or other equivalent statement must not be used to compound for these purposes.

(f) If a component included on the published on the 503A Category 1 interim bulk drug substances list is used, it must be found suitable for sterile drug preparations as provided in USP Chapter 797, Section 9.3 Components. The facility's SOPs must establish a process to determine the quality of the API.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005~~,~~ and 4126.8, Business and Professions Code.

1736.10. Sterilization and Depyrogenation.

In addition to the requirements in USP Chapter 797, the following requirements apply where applicable.

(a) Dry heat depyrogenation shall be done in compliance with USP Chapter 1228.1, Dry Heat Depyrogenation.

(b) Sterilization by filtration shall be done in compliance with USP Chapter 1229.4, Sterilizing Filtration of Liquids. Filter dimensions and the CSP to be sterilized by filtration shall permit the sterilization process to be completed without the need for replacement of the filter during the process.

(c) Steam sterilization shall be done in compliance with USP Chapter 1229.1, Steam

Sterilization by Direct Contact.

(d) Dry heat sterilization shall be done in compliance with USP Chapter 1229.8, Dry Heat Sterilization.

(e) No compound of a CSP from nonsterile components shall be prepared when the licensed location cannot also sterilize the CSP as described in this section.

(f) Sterilization of supplies and ~~/or~~ container–closure systems shall be done in compliance with USP Chapter 1229, Sterilization of Compendial Articles.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.

1736.11. Master Formulation and Compounding Records.

In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.

(a) A CSP shall not be compounded until the facility has first prepared a written master formulation record in compliance with USP Chapter 797 and that record includes the following additional elements:

(1) If a source is referenced to support the assigned beyond-use date (BUD), each source referenced shall be readily retrievable at the time of compounding and shall be maintained for three years from the date each CSP is dispensed.

(2) Instructions for storage and handling the compounded drug preparation.

(b) When a particular drug preparation is not routinely compounded at a facility, the master formulation record for that preparation may be recorded on the prescription document itself. This record shall comply with USP Chapter 797 and this section.

(c) A compounding record (CR) shall be maintained and, upon request, be produced ~~a~~ as a single document. The document shall satisfy the requirements of USP Chapter 797, and also contain the following:

~~(1) The date and time of preparation. The time of preparation is the time when compounding the CSP started, which also determines when the assigned BUD starts.~~

~~(2)~~ (1) The assigned internal identification number, which shall be unique for each CR.

~~(3)~~ (2) The manufacturer, lot number, and expiration date for each component for the CSP.

~~(4)~~ (3) The total quantity compounded including the number of units made and

either the volume or the weight of each unit.

~~(5)~~ (4) The identity of ~~each~~ personnel ~~person~~ performing the compounding, **the** pharmacist~~that~~ who has direct ~~oversight~~ supervision and control of compounding, and **the** pharmacist verifying the final drug preparation**, if different**.

~~(6)~~ (5) When applicable, endotoxin level calculations and results.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4081, 4126.8, 4127, and 4169 Business and Professions Code.

1736.12 Release Inspections and Testing.

In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.

(a) A pharmacist performing or who has direct supervision and control of compounding personnel~~supervising sterile compounding~~ is responsible for ensuring the integrity, quality, and labeled strength of a CSP until the beyond use date indicated on the label provided the patient or the patient's agent follows the label instructions provided on the CSP for storage and handling after receiving the CSP.

(b) A pharmacist performing or who has direct supervision and control of compounding personnel~~supervising sterile compounding~~ is responsible for ensuring validation of an alternative method for sterility testing is done in compliance with USP Chapter 1223, Validation of Alternative Microbiological Methods and shall receive and maintain documentation of the method-suitability for each CSP formulation for which the alternate method is used.

(c) A pharmacist performing or who has direct supervision and control of compounding personnel ~~supervising sterile compounding~~ is responsible for ensuring injectable CSPs made from nonsterile components, regardless of USP Category, are tested to ensure that they do not contain excessive bacterial endotoxins, as established in USP Chapter 85, Bacterial Endotoxins. Results must be reviewed and documented in the compounding record prior to furnishing.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4081, 4126.8, 4127, 4169, and 4332 Business and Professions Code.

1736.13. Labeling.

In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.

(a) A CSP label shall also include all of the following:

(1) Route of intended administration;

(2) For CSPs administered by infusion, ~~T~~the solution utilized~~, if applicable~~;

(3) Instructions for administration;

(A) For ~~an admixed~~ CSPs administered by infusion, the rate of infusion, or range of rates of infusion as prescribed, or the duration for the entire CSP to be administered. **A health care facility licensed pursuant to Health and Safety Code Section 1250 may reference the patient's chart in lieu of rate of infusion when a patient's condition requires a variable rate.**

(4) Name of compounding facility and dispensing facility (if different).

(b) The label for ~~A~~any CSP dispensed or ready to be dispensed to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5. A CSP that is administered to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility, or a juvenile detention facility shall be labeled with **the** patient**'s** name, the directions for the use of the drug, and **the** date of issuance, but is otherwise exempt from these requirements.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4076, 4123, 4126.8, and 4127, Business and Professions Code.

1736.14. Establishing Beyond-Use Dates.

In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.

(a) A CSP's beyond-use date (BUD) shall not exceed:

(1) The chemical and physical stability data of the active pharmaceutical ingredient(s) and any added substances in the preparation;

~~**(A) Nothing in this section shall prohibit the allowances in USP 797 section 14.3 for pH-altering solutions.**~~

(2) The compatibility of the container–closure system with the finished preparation (e.g., possible leaching, interactions, and storage conditions); and

(3) The shortest remaining expiration date or BUD of any of the starting components. **Nothing in this paragraph prohibits the allowances in USP Chapter 797 Section 14.2 for pH-altering solutions.**

(b) A CSP labeled with a BUD with only a date shall expire at 11:59 p.m. **(23:59)** on that

date.

(c) ~~Prior to furnishing a CSP,~~ When sterility ~~and/~~or endotoxin testing ~~are~~ **is** required, the pharmacist performing or with direct supervision and control of personnel ~~ing sterile~~ compounding is responsible for ensuring ~~that sterility and endotoxin~~such testing ~~for BUD determination~~ is performed. Test results shall be reviewed ~~the results~~prior to furnishing a CSP. Results must be within acceptable USP limits. Test results ~~must~~ shall be retained as part of the compounding record.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4076, and 4126.8, Business and Professions Code.

1736.15. Use of Conventionally Manufactured Products as Components.

In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.

(a) A single-dose container entered or punctured outside of an ISO Class 5 area, must be discarded immediately.

(b) A single-dose container entered or punctured inside of an ISO Class 5 area must be discarded within 12 hours.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.

1736.16. Use of CSPs as Components.

In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.

(a) A compounded stock solution intended for use in a CSP must comply with all provisions of this article and USP Chapter 797 Category 1, Category 2, or Category 3.

(b) Nothing in this section shall prohibit the use of a CSP obtained from a California licensed outsourcing facility.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4127.2, and 4127.8, Business and Professions Code.

1736.17. Standard Operating Procedures (SOPS).

In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.

(a) Standard operating procedures (SOPs) for sterile compounding shall be followed and shall:

(1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding; and

(2) Define the following:

(A) Methods by which the pharmacist compounding or supervising the compounding will ensure the quality of compounded drug preparations;

(B) If applicable, ~~P~~procedures for handling, compounding, and disposal of infectious materials. The SOPs shall describe the facility protocols for cleanups and spills in conformity with local health jurisdictional standards;

(C) The methods ~~**a pharmacist will**~~ used to determine and approve the ~~***ingredients***~~ ***components*** and the compounding process for each preparation before compounding begins~~:~~ ***, including components referenced in section 1736.9(f)***; and

(D) The method for complying with all other requirements specifically defined in the SOPS.

~~***(E) The methods by which the pharmacist compounding or supervising the compounding pursuant to section 1736.9(f) (e)(2) related to use of a bulk drug substance published in the section 503A Category 1 bulk substances list, will ensure each lot of the bulk drug substance is representatively sampled per USP Chapter 1097 (bulk powder sampling procedures), tested, and found to be in compliance with at least:***~~

~~***(i) USP Chapter 1, Injections and Implanted Drug Products (Parenterals) – Product Quality Tests***~~

~~***(ii)USP Chapters 232 and 233 related to Elemental Impurities.***~~

~~***(iii) USP Chapter 467 – Residual Solvents.***~~

~~***(iv)USP Chapter 85 – Bacterial Endotoxins, and***~~

~~***(v) any other USP Chapters deemed appropriate based on the clinical judgment of the pharmacist developing the SOPs.***~~

~~***(F) Nothing in paragraph (E) requires the facility to perform this testing when it is performed by the manufacturer, repackager, or wholesaler and appropriate documentation of such testing is provided to the facility.***~~

(b) The SOPs shall specify the steps to be taken if a classified area(s) including PEC, fails to meet the specified ISO classification, including the investigative and corrective actions, allowable activities, and retesting procedures. This subsection shall also include actions to be taken if the compounding area or equipment is rendered

unusable or in downtime situations.

(c) The SOPs shall specify steps to be taken when the microbiological air and surface monitoring action levels are exceeded including the investigative and corrective actions, allowable activities, and resampling procedures.

(d) The SOPs shall specify the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the anteroom, entering a PEC, and entering the SCA. These SOPs must define at a minimum what product is to be used, the contact ~~dwell~~ time required, and **~~how~~ the method to ensure** ~~dwell~~ contact time **is achieved** **~~will be monitored and documented~~**.

(e) The SOPs shall specify the frequency and processes for cleaning, maintenance, and calibration of equipment, supplies and components, including when incubation of samples is taking place, such that samples are not compromised. All cleaning, maintenance, and calibration shall be documented and dated as defined in the SOPs.

(f) The SOPs shall specify which pharmacist is responsible for the review of all complaints related to a potential quality problem with a CSP and all adverse drug experiences in the event that the PIC is not available within 72 hours of the receipt of the complaint or occurrence.

(g) There shall be written procedures for qualification of storage, shipping containers and transportation of temperature sensitive CSPs to preserve quality standards for integrity, quality, and labeled strength.

(h~~f~~) The pharmacist-in-charge (PIC) shall review the SOPs on an annual basis. The PIC shall document such review consistent with the SOPs. The SOPs shall be updated to reflect changes to compounding processes, facility changes, and other changes that impact the CSP. Such SOP changes shall be disseminated to the compounding personnel prior to implementation**. Documentation of compliance with the subdivision shall be maintained for three years.**

(~~ih~~) Failure to follow written SOPs shall constitute a basis for enforcement action.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5 and 4332, Business and Professions Code.

1736.18. Quality Assurance and Quality Control.

In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.

(a) The quality assurance program shall comply with section 1711 and the standards contained in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding.

In addition, the **facility's quality assurance** program shall include the following:

(1) A written procedure for ~~scheduled~~ action, such as a recall, in the event any compounded drug preparation is discovered to be outside the expected standards for integrity, quality, or labeled strength.

(2) A written procedure for responding to out-of-range temperature variations within the medication storage areas where a furnished drug may be returned for furnishing to another patient.

(b) Recalls and adverse drug experiences**,** ~~event~~ as defined in 21 CFR **section** 310.305(b), reporting ~~**must**~~ **shall** be completed in compliance with relevant provisions of law.

(c) In addition to subsection (b), **the pharmacist-in-charge shall initiate a review of any** ~~**all**~~ complaints made to the facility related to a potential quality problem with a CSP and **any** ~~**all**~~ adverse drug experiences ~~events~~ ~~**shall be reviewed by the pharmacist-in-charge**~~ within 72 hours of receipt of the complaint or occurrence of the adverse drug experience. Such review shall be documented and dated as defined in the SOPs.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4127.2, and 4127.8, Business and Professions Code.

1736.19. CSP Handling, Storage, Packaging, Shipping, and Transport.

In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.

Packaging materials shall protect CSPs from damage and~~,~~ leakage, ~~contamination, degradation, and adsorption~~ while also preventing transportation personnel from inadvertent exposure.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.

1736.20. Documentation.

In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.

(a) Records shall be maintained as required by USP Chapter 797 and this article, in a readily retrievable form, for at least three years from the date the record was created or relied upon. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070.

(b) Records ~~created~~ shall be created and maintained in a manner to provide an audit trail for revisions and updates of each record document. Prior versions of each record must be maintained, for at least three years from the date the record was created, **modified,** or relied upon, in a readily retrievable format and include the changes to the document, identification of **the** individual who made the change, and the date of each change.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4081, 4105, 4126.8, 4127 and 4332, Business and Professions Code.

1736.21. Compounding Allergenic Extracts.

In addition to the requirements in USP Chapter 797, the following requirements apply to allergenic extracts ~~sterile compounding~~.

(a) Any allergenic extract compounding shall take place in a dedicated allergenic extract compounding area (AECA) or PEC. ~~No other CSP may be made in this PEC.~~ No other CSP may be made in this PEC at the same time allergenic extract compounding is occurring. Work surface of the PEC must be cleaned and disinfected immediately after allergenic extract compounding.

(b) Compounding of allergenic extracts are limited to patient-specific prescriptions. ~~and the conditions limited to Category I and Category 2 CSPs as specified in USP Chapter 797.~~

~~**(c) Any compounded stock allergy solution shall comply with the requirements established in USP Chapter 51, Antimicrobial Effectiveness Testing and the requirement established in USP Chapter 1207, Sterile Product Packaging – Integrity Evaluation related to container closure. A compounding record is required for any compounded stock solution.**~~

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.

Proposal to Add Article 4.7 and add new titles and section 1737 – 1737.18 to Division 17 ~~or~~ of Title 16 of the California Code of Regulations to read as follows:

Article 4.7 Hazardous Drugs

1737. Handling of Hazardous Drugs.

In addition to the requirements in United States Pharmacopeia (USP) General Chapter 800 (USP Chapter 800), *Hazardous Drugs – Handling in Healthcare Setting*, ~~This~~ this article applies to the ~~handling~~ compounding of Hazardous Drugs (HDs) or **~~performing "other manipulations" included in Table 1 of the Chapter~~ crushing or splitting tablets or opening capsules** of antineoplastic HDs, ~~of Hazardous drugs~~ **~~established by United States Pharmacopeia (USP) General Chapter 800 (USP Chapter 800), titled *Hazardous Drugs – Handling in Healthcare Setting*. In addition to the standards in the USP Chapter 800, Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article.~~**

(a)A licensee performing hazardous drug (HD) compounding shall comply with this article as well as the non-sterile and sterile compounding requirements, as applicable, in Article 4.5 and Article 4.6.

(b) Additional safety and health requirements are included in the California Code of Regulations, Title 8, and are enforced by the Division of Occupational Safety and Health.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.

1737.1. Introduction and Scope.

~~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 the requirements in USP Chapter 800, the following requirements apply to the compounding of Hazardous Drugs.

(a) In addition to ~~providing~~ the provisions in ~~consultation in compliance with~~ section 1707.2, consultation **includes ~~shall be provided to the patient and/or patient's agent concerning~~** handling and disposal of a~~n~~ compounded HD or related supplies furnished. A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has

implemented a written policy about discharge compounded medications which meets the requirements of Business and Professions Code Section 4074.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.

1737.2. List of Hazardous Drugs.

In addition to the standards in ~~the~~ USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed. ~~Hazardous Drugs—Handling in Healthcare Setting shall meet the following requirements of this article.~~

(a) The facility's list of HDs as required by USP Chapter 800 must be reviewed and approved by ~~the designated person and~~ the pharmacist-in-charge (PIC), **or the** professional director of a clinic, or **the** designated representative-in-charge, as applicable. **Approval shall be documented at least every 12 months.**

(1) In a pharmacy, T~~t~~he designated person**(s)** must be ~~a single individual~~ approved by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the handling of hazardous drugs. The designated person**(s)** shall not exceed the scope of their issued license. When **a** ~~the~~ designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the judgment of a pharmacist. ~~Approval shall be documented at least every 12 months.~~

(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.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.

1737.3. Types of Exposure.

In addition to the standards in ~~the~~ USP Chapter 800, the following requirements apply to a facility that compounds HDs or ~~performs~~ **crushes or splits tablets or opens capsules of antineoplastic HDs ~~"other manipulations" included in Table 1 of the Chapter of antineoplastic HDs~~**. ~~Hazardous Drugs—Handling in Healthcare Setting shall meet the following requirements of this article.~~

~~Each premises where~~ Any facility where compounding of HDs is performed or ~~one~~ where **crushing or splitting tablets or opening capsules of antineoplastic HDs ~~"other manipulations" included in Table 1 of the Chapter of antineoplastic HDs~~** is performed

~~are handled~~ shall ensure that all employees are aware of the types of HD exposures that may occur as referenced in **~~the~~** USP Chapter 800. This shall be documented in SOPs and training documents.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.

1737.4. Responsibilities of Personnel Handling Hazardous Drugs.

In addition to the standards in **~~the~~** USP Chapter 800, the following requirements apply to the compounding of HDs or performing **crushing or splitting tablets or opening capsules of antineoplastic HDs ~~"other manipulations" included in Table I of the Chapter~~** of antineoplastic HDs.~~Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article.~~

The PIC, designated representative-in-charge, or professional director, as applicable, shall be responsible for all activities and decisions made or approved by the designated person.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.

1737.5. Facilities and Engineering Controls.

In addition to the standards in USP Chapter 800, the following requirements apply to any facility where compound**ings** of HDs is performed.~~Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article.~~

(a) When containment primary engineering controls (C-PECs) used for nonsterile and sterile HDs are placed in the same room, biannual certification shall document that the room can continuously maintain an ISO 7 classification throughout the nonsterile compounding activity. Specific standard operating procedures (SOPs) shall be written to address the maintenance of the ISO 7 classification.

(b) A biological-safety cabinet as defined in USP Chapter 800 Class II Type A1 shall not be used for sterile compounding of a volatile HD.

~~(c)~~ ~~Where a pass-through is installed in a containment secondary engineering control (C-SEC), the doors must be gasketed and interlocking.~~ **~~Effective [OAL insert six months following the effective date]~~** ~~A~~ **~~a pass-through is not allowed between the hazardous drug buffer room~~** ~~C-SEC~~ **~~into an unclassified space.~~**

(**~~d~~c**) Where there is a pass-through ~~door is installed or replaced~~ in a **containment** secondary engineering control (C-SEC), the doors must be gasketed and

interlocking by January 1, 2027. ~~after [OAL insert effective date] the pass-through door shall be a HEPA purge type.~~

(**ed**) On or after January 1, 2028, prior to installing a new pass-through, a facility shall consider the use of a HEPA purge type pass-through. Documentation shall be maintained showing compliance with this requirement if such a pass-through is not used.

(~~e~~**fe**) **Where sterile hazardous compounding in is performed, F**~~f~~acility room pressure monitoring equipment shall be placed consistent with CETA Guidelines CAG-003:2022. SOPs shall address corrective and remedial actions in the event of pressure differentials ~~and air changes per hour~~ excursions.

(~~f~~**gf**) Containment Supplemental Engineering Controls (CSTDs) shall not be used to extend the in-use time, BUD, or expiration of any manufactured product or HD CSP.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.

1737.6. Environmental Quality and Control.

In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed. ~~Hazardous Drugs—Handling in Healthcare Setting shall meet the following requirements of this article.~~

The **premises shall consider environmental wipe sampling, and** SOPs ~~**of a premises** where HDs are handled~~ shall **address describe the consideration of and provisions for** environmental wipe sampling for HD surface residue~~**, its frequency, and areas of testing**, levels of measurable contamination, and actions when those levels are exceeded~~. **Nothing in this section is intended to require the use of environmental wipe sampling.**

~~(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).~~

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.

1737.7. Personal Protective Equipment (PPE).

In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed. ~~Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article.~~

~~**(a) Two pairs of chemotherapy gloves that meet the ASTM D-6978 standard shall be worn for handling HD waste, cleaning HD spills, and performing routine cleaning in HD areas.**~~

~~**(b) The outer pair of chemotherapy gloves that meets the ASTM D-6978 standard chemotherapy gloves shall be changed** every 30 minutes during HD compounding unless otherwise **as recommended by the manufacturer's documentation. Documentation from the manufacturer shall be readily retrievable. For sterile HD compounding, both pairs of gloves labeled to meet the ASTM D-6978 standard shall be sterile.**~~

(~~c~~**a**) Outer gloves used for HD compounding shall be ***carefully removed and discarded immediately into a waste container approved for trace contaminated waste inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC as established in USP 800 Section 7.6*** ~~***changed between each different HD preparation, unless preparing multiple HD preparations of the same drug or preparing multiple HD preparations for a single patient***~~.

(~~d~~**b**) PPE removal process shall be done in a manner ~~shall be removed~~ to avoid transferring contamination to skin, the environment, and other surfaces. Outer 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.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.

1737.8. Hazard Communication Program.

In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed. ~~Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article.~~

The designated person shall be involved in ~~develop~~ the premise's hazardous communication program and document the program in the SOPs and training documents.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.

1737.9. Personnel Training.

In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed or ~~**one**~~ where ~~**"other manipulations" included in Table 1 of the Chapter of antineoplastic HDs is**~~ **crushing or splitting tablets or opening capsules** of antineoplastic HDs is performed.~~Hazardous Drugs—Handling in Healthcare Setting shall meet the following requirements of this article.~~

(a) Any person assigned to provide the training specified in this Article shall have demonstrated competency in the skills in which the person will provide training or observe and measure competency described in the facility's SOPs as referenced in section 1737.17. Documentation must be maintained demonstrating compliance with training requirements and demonstrating competency must be maintained.

(b) All personnel responsible for ~~handling~~ compounding HDs or ~~**"other manipulations" crushing or splitting tablets or opening capsules**~~ of antineoplastic HDs who fail any aspect of ongoing evaluation and training in ~~handling~~ compounding or ~~**"other manipulations" crushing or splitting tablets or opening capsules**~~ of antineoplastic HDs shall not ~~handle~~ compound HDs or perform ~~**"other manipulations" crushing or splitting tablets or opening capsules of antineoplastic HDs**~~ until after successfully passing reevaluations in the deficient area(s), as detailed in the facility's SOPs. Any failure in personnel competency shall comply with the provisions of **sections** 1735.2(c) or 1736.2(d), as applicable.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.

1737.10. Receiving.

In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed.~~Hazardous Drugs—Handling in Healthcare Setting shall meet the following requirements of this article.~~

All HD APIs and antineoplastic HDs shall be transported ~~shipped and received from~~by the supplier in segregated impervious plastic and labeled **as** ~~"~~"Hazardous Drugs"~~"~~ on the outside of the delivery container.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.

1737.11. Labeling, Packaging, Transport and Disposal.

In addition to the standards in USP Chapter 800, the following requirements apply to ~~the~~ a facility where compounding of HDs is performed. ~~Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article.~~

(a) The label for ~~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. A compounded HD preparation that is administered to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility~~,~~ or a juvenile detention facility shall be labeled with **the** patient name, the directions for the use of the drug, and **the** date of issuance, but is otherwise exempt from these requirements.

(b) All ~~HD APIs and~~ compounded antineoplastic HDs shall be transported from the facility in an impervious plastic container and labeled as Hazardous Drugs ~~HD~~ on the outside of the container, **unless the label is visible through the outer container.**

(c) When furnishing a compounded antineoplastic HD for administration within a health care facility licensed pursuant to Health and Safety Code section 1250, the HD shall be placed in a plastic container and labeled as a hazardous drug on the outside of the container or with a label that is visible through the ~~outside~~ outer container.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.

1737.12. Dispensing Final Dosage Form.

In addition to the standards in USP Chapter 800, **~~Hazardous Drugs –~~** the following requirements apply to a facility where compounding of HDs is performed.~~Handling in Healthcare Setting shall meet the following requirements of this article.~~

Equipment used in nonsterile HD compounding shall be dedicated for use with HDs and shall be decontaminated after each use.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.

1737.13. Compounding.

In addition to the standards in USP Chapter 800, the following requirements apply to ~~the~~ a facility where compounding of HDs is performed. ~~Hazardous Drugs—Handling in Healthcare Setting shall meet the following requirements of this article.~~

(a) If a~~A~~ disposable preparation mat is used for compounding a CSP it must be sterile and it must be changed immediately if a spill occurs, after each different HD preparation **unless multiple preparations of the same drug or for a single patient is occurring**, and at the end of the daily compounding activity.~~shall be placed on the work surface of the C-PEC when compounding HD preparations. Where the compounding is a sterile preparation, the preparation mat shall be sterile. The preparation mat shall be changed immediately if a spill occurs, after each HD drug, and at the end of daily compounding activity.~~

(b) Only one HD preparation may be handled in a C-PEC at one time, **unless the multiple HD preparations are of the same drug, or are multiple HD preparations for a single patient**.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.

1737.14. Administering.

In addition to the standards in USP Chapter 800~~, Hazardous Drugs—Handling in Healthcare Setting~~ a facility where compounding of HDs is performed shall meet the following requirements of this article.

(a) When ~~dispensing~~ furnishing ~~an~~ a**n infused** compounded antineoplastic HD ~~to a patient or patient's agent~~ for administration, the ~~pharmacy~~ facility shall~~:~~

~~**(1) Place the HD in a decontaminated impervious plastic container with an HD label on the outside of the container; and**~~

~~**(2) For an infused antineoplastic HD,**~~ attach and prime ~~all~~ tubing and attach a CSTD when appropriate.

(b) When ~~furnishing~~ dispensing ~~an~~ a compounded antineoplastic HD to a patient or patient's agent, **the pharmacy shall provide, or offer for purchase, ~~,~~** a sufficient supply of ASTM D-6978 standard **chemotherapy** gloves~~,~~ ~~that meet the ASTM D-6978 standard~~ **~~and shall be provided to the patient or the patient's agent~~**, to allow for appropriate **~~administration~~**, handling, and disposal of the HD. ~~drugs by the patient or~~

~~the patient's agent shall be provided.~~ **A compounded antineoplastic HD preparation that is administered to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code is exempt from this requirement..**

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.

1737.15. ~~Deactivation, Decontamination,~~ Deactivating, Decontamination, Cleaning, and Disinfecting.

In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding HDs is performed or **~~one~~** where **crushing or splitting tablets or opening capsules ~~"other manipulations" included in Table 1 of the Chapter~~** of antineoplastic HDs is performed. ~~Hazardous Drugs—Handling in Healthcare Setting shall meet the following requirements of this article.~~

(a) Deactivating, decontaminating, cleaning, disinfecting, and sporicidal agents shall be used in accordance with manufacturers' specifications**, or subsequent manufacturer approved studies,** and shall be surface compatible.

(b) Agents used for deactivation, decontamination, cleaning, and disinfecting all areas and equipment involved in the compounding of HDs ~~handling~~ or performing **crushing or splitting tablets or opening capsules ~~"other manipulations"~~** of antineoplastics HDs shall be applied through the use of wipes wetted with the appropriate solution ~~and shall not be applied or delivered to the wipe by use of a spray bottle to avoid spreading HD residue~~.

~~(c) SOPs shall include procedures for deactivation and decontamination of the HD preparation container closure and shall be approved by the pharmacist-in-charge or professional director of a clinic, as applicable.~~

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, and 4126.8, Business and Professions Code.

1737.16. Spill Control.

In addition to the standards in USP Chapter 800, the following requirements apply to **~~the~~** a facility where compounding of HDs is performed.~~Hazardous Drugs—Handling in Healthcare Setting shall meet the following requirements of this article~~.

~~The premises shall 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~~ compounded.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005 and 4126.8, Business and Professions Code.

1737.17. Documentation and Standard Operating Procedures (SOPs).

In addition to the standards in USP Chapter 800, the following requirements apply to the compounding of HDs or performing **crushing or splitting tablets or opening capsules of antineoplastic HDs ~~"other manipulations" included in Table 1 of the Chapter of antineoplastics HDs~~** .~~Hazardous Drugs – Handling in Healthcare Setting shall meet the following requirements of this article.~~

(a) A~~ny~~ ~~premises~~ facility ~~engaged in the compounding or handling of HDs~~ shall maintain and follow written SOPs for all situations in which HDs are compounded **or crushing or splitting tablets or opening capsules of** antineoplastic HDs **is performed are ~~"otherwise manipulated"~~**.

(b) A facility where compounding **of** HDs is performed or **~~one~~ where crushing or splitting tablets or opening capsules of ~~"other manipulations"~~** antineoplastic HDs is performed shall have ~~The~~ SOPs ~~for compounding or handling HDs shall~~ that include at least the following:

(1) Hazard communication program
(2) Occupational safety program
(3) Designation of HD areas, if compounding
(4) Receipt, if compounding
(5) Storage, if compounding
(6) Compounding, if applicable
(7) Use and maintenance of proper engineering controls (e.g., C-PECs, C-SECs, and CSTDs), if applicable
(8) Hand hygiene and use of PPE based on activity (e.g., receipt, transport, compounding, manipulation, administration, spill, and disposal), as applicable
(9) Deactivation, decontamination, cleaning, and disinfection
(10) Dispensing, if applicable
(11) Transport, if compounding
(12) Administering, if applicable
(13) Environmental monitoring (e.g., wipe sampling), if compounding
(14) Disposal, if compounding
(15) Spill control, if compounding
(16) Medical surveillance, if compounding

(c) The pharmacist-in-charge, professional director of a clinic, or designated representative-in-charge, as applicable, shall work with the ~~entity's~~ facility**'s** designated person to ensure ~~HD handling~~ SOPs are reviewed at least every 12

months and this review is documented. **Documentation of compliance with the subdivision shall be maintained for three years.**

(d) SOPs shall be updated whenever changes are implemented. Such changes shall be disseminated in a written format to the staff responsible for ~~handling~~ HDs prior to implementation. All notifications of such changes and the changes shall be documented in SOPs and training documents.

(e) Failure to follow written SOPs constitutes a basis for enforcement action.

Note: Authority cited: Sections 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005and 4126.8, Business and Professions Code.

Repeal sections 1708.3, 1708.4, and 1708.5 of Article 2, and add new Article 4.8, and titles and sections 1738 through 1738.14, to Article 4.8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 4.8 Radiopharmaceutical- Preparation, Compounding, Dispensing, and Repackaging

1738. Definitions.

In addition to the terms defined in United States Pharmacopeia (USP) General Chapter 825 (USP Chapter 825), titled Radiopharmaceuticals- preparation, compounding, dispensing, and repackaging, the following definitions apply to this article and supplement the definitions provided in USP Chapter 825 radiopharmaceutical processing activities.

~~In addition to the definitions contained in USP Chapter 825, the following definitions apply to this Article and supplement the standards established in USP Chapter 825.~~

(a) "Added substances" means ingredients that are necessary to compound a preparation but are not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the term's inactive ingredients, excipients, and pharmaceutical ingredients.

(b) "Component" means any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.

(c) "Designated person" means a pharmacist identified as assigned, responsible, and accountable for the performance and operation of the radiopharmaceutical processing facility and for personnel who prepare, compound, dispense, and repackage radiopharmaceuticals. **Nothing in this definition prohibits the PIC from also serving as the designated person.**

(d) "Processing," "processed," or "processing activity" means the preparation, compounding, repackaging, or dispensing of a radiopharmaceutical.

Note: Authority cited: Sections 4005, 4008, and 4126.8, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, and 4306.5, Business and Professions Code.

1738.1. Introduction.

In addition to the standards in ~~the~~ USP Chapter 825, the processing of Radiopharmaceuticals shall meet the requirements of this section.

~~This Article applies to radiopharmaceuticals as defined in USP Chapter 825. In addition to the requirements provided in this Article, the processing of radiopharmaceuticals shall comply with the standards established by United States Pharmacopeia General Chapter 825, titled *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging* ("USP Chapter 825" for the purposes of this Article).~~

In addition to the standards contained in USP Chapter 825, the following apply to this Article and supplement the standards established in USP Chapter 825

(a) The use of technologies, techniques, material, and procedures not described in USP **Chapter** 825 shall be based upon published peer-reviewed literature or documents and meet FDA approved labeling requirements in accordance with sections 201.56 and 201.57 of title 21~~,~~ **of the** Code of Federal Regulations, showing the technologies, techniques, material, and procedures to be equivalent or superior to those described in USP Chapter 825.

(b) Processing with human whole blood or human whole blood derivatives shall be done in compliance with Health and Safety Code section 1602.5.

Note: Authority cited: Sections 4005, 4008, and 4126.8, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, and 4306.5, Business and Professions Code.

1738.2. Radiation Safety Considerations.

In addition to the standards in the USP Chapter 825, the processing of Radiopharmaceuticals shall meet the requirements of this section.
~~In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the following radiation safety requirements of this section.~~

(a) Radiation detectors and measuring devices, and other necessary equipment, may be placed inside an ISO Class 5 PEC but must be placed in a manner that minimizes disruptions of airflow.

(b) Disposable absorbent pads shall be changed after each type of radiopharmaceutical processing.

(c) Any deviation made to lower radiation exposure to workers shall be evaluated and documented in an SOP by the designated person prior to the deviation occurring. Exceptions to the environmental controls requirements must be documented in the specific radioactive materials license conditions issued by the California Department of Public Health pursuant to section 30190 of Title 17 of the California Code of Regulations, or a specific radioactive materials license issued by another state or the United States Nuclear Regulatory Commission pursuant to ~~**pursuant to**~~section 32.72 of title 10 of the Code of Federal Regulations.

Note: Authority cited: Sections 4005, 4008, and 4126.8, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, and 4306.5, Business and Professions Code.

1738.3. Immediate Use of Sterile Radiopharmaceuticals.

The processing of radiopharmaceuticals for immediate use may only be done in a patient care setting meeting the applicable requirements in this Article. The patient care facility shall maintain all records required in Section 9 of USP Chapter 825 in accordance with Business and Professions Code section 4081.

Note: Authority cited: Sections 4005, 4008, and 4126.8, Business and Professions Code. Reference: Sections 4005, 4081, 4126.8, 4301, and 4306.5, Business and Professions Code.

1738.4. Personnel Qualifications, Training, and Hygiene.

In addition to the requirements in USP Chapter 825, the processing of radiopharmaceuticals shall ~~comply~~ meet ~~with all of~~ the requirements of this section.

(a) Processing personnel experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection, or other conditions that could contaminate a sterile radiopharmaceutical or the environment shall not be allowed to enter the compounding area unless approved by the designated person. Any approvals provided by the designated person shall be documented and the record shall include the name of the individual granted approval, the approval date and time, the reason for granting approval, and the identification of the designated person making the decision.

(b) The pharmacist with direct ~~oversight~~ supervision and control over personnel performing radiopharmaceutical processing shall, as defined in the facility's SOPs, demonstrate proficiency in the skills necessary to ensure the integrity, strength, quality, and labeled strength of radiopharmaceuticals.

(c) Aseptic manipulation competency initial training and competency and ongoing training and competency documentation shall include the Primary Engineering Control (PEC's) type and PEC unique identifier used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and materials used in aseptic compounding. Aseptic qualifications from one premises may be used for another premises if all of the following conditions are met:

(1) The SOPs related to compounding are identical.
(2) The SEC facility designs are sufficiently similar to accommodate the use of the same SOPs.

(3) The PECs are of the same type and sufficiently similar to accommodate the use of the same SOPs describing use and cleaning.

(d) SOPs must clearly define the acceptable use and cleaning for reusable gowns in order to prevent possible contamination of the Sterile Radiopharmaceuticals and designated compounding area. The facility's SOPs must describe the process to be followed should the facility allow for the reuse of garb.

(e) Eyeglasses shall be cleaned as part of hand hygiene and garbing, consistent with the standards specified in the SOPs.

(f) Garb shall be donned and removed in an ante-area or immediately outside the segregated radiopharmaceutical processing area (SRPA). Donning and doffing garb shall not occur in the anteroom at the same time unless the SOPs define specific processes that must be followed to prevent contamination.

(g) Any person assigned to provide the training specified in this article shall have demonstrated competency in the skills in which the person will provide training or observe and measure competency described in the facility's SOPs as referenced in section 1738.14. Documentation must be maintained demonstrating compliance with training requirements and demonstrating competency must be maintained.

(h) All personnel working with radiopharmaceuticals who fail any aspect of ongoing evaluation and training in personnel qualifications shall not work with radiopharmaceuticals until after successfully passing reevaluations in the deficient area(s), as detailed in the facility's SOPs.

Note: Authority cited: Sections 4005, 4008, and 4126.8, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, and 4306.5, Business and Professions Code.

1738.5. Facilities and Engineering Controls.

In addition to the requirements in USP Chapter 825, the processing of radiopharmaceuticals shall ~~comply~~ meet ~~with all of~~ the requirements of this section.

(a) A sink used for compounding or hand hygiene shall not be part of a restroom or water closet.

(b) The temperature shall be monitored either manually or by a continuous recording device in the SRPA and classified areas each day that processing is performed.

(c) Storage and elution of non-direct infusion radionuclide generators shall take place in an ISO Class 8 or better area.

(d) If an SRPA is used:

(1) Except for walls, the SRPA's visible perimeter shall be at least 1 meter from all sides of the PEC or in a separate room.

(2) Surfaces within the SRPA shall be smooth, impervious, free from cracks and crevices, and non-shedding, so they can be easily cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate.

~~**(3 e) Compounding shall not take place in the SRPA.**~~

(~~e~~ **f e**)(1) Testing and certification of all classified areas shall be completed by a competent individual. A competent individual is a technician who possesses a current accreditation issued by The Controlled Environment Testing Association (CETA), or who is under the direct supervision of an individual who possesses a current accreditation issued by CETA. The facility shall review and maintain a copy of the accreditation documentation in accordance with requirements in section 1738.9.

(2) Certification shall be completed consistent with the provisions established in USP Chapter 797, titled "Pharmaceutical Compounding—Sterile Preparations" (USP <797>). CETA standard(s) used to perform certification testing in all classified areas shall be recorded on the certification report as specified in USP Chapter 797.

(~~f~~ **e f**) SOPs shall specify steps to be taken if any classified area fails to meet the specified ISO classification, including the investigative and corrective actions, allowable activities, and retesting procedures.

(~~g~~ **h g**) All classified spaces and equipment must be recertified when there is any change in the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes when the PEC is moved, repaired, or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or when improper aseptic techniques are observed. SOPs must address the conditions under which recertification must also be completed when temporarily moving or permanently relocating a PEC.

(h) Activities and tasks carried out within the SRPA and classified areas shall be limited to only those necessary for processing a radiopharmaceutical.

(i) Food, drinks, and materials exposed in patient care and treatment areas must not enter SRPA or classified areas.

~~(j) A dynamic airflow smoke pattern test must be performed initially and at least every 6 months for all classified spaces and equipment. All dynamic airflow smoke pattern tests shall be immediately retrievable during inspection. A copy of the test shall be provided to the Board's inspector if requested in accordance with the timeframes set forth in Section 4105 of the Business and Professions Code.~~

Note: Authority cited: Sections 4005, 4008, and 4126.8, Business and Professions Code. Reference: Sections 4005, 4081, 4105, 4126.8, 4301, and 4306.5, Business and Professions Code.

1738.6. Microbiological Air and Surface Monitoring.

In addition to the requirements in USP Chapter 825, the processing of radiopharmaceuticals shall ~~comply~~ meet ~~with all of~~ the requirements of this section.

(a) SOPs shall specify steps to be taken for processing radiopharmaceuticals when the microbiological air and surface monitoring action levels are exceeded, including the investigative and corrective actions, allowable activities, and resampling procedures.

~~(b) In addition to the SOPs at a minimum every 6 months, air and surface sampling results shall be identified to at least the genus level, regardless of the colony forming units (CFU) count, to trend for growth of microorganisms. Trends of microorganism growth must be identified and evaluated. SOPs shall specify the appropriate action(s) necessary to remedy identified trends.If lab is unable to identify to the genus level, the facility shall maintain with the sampling results documentation that no identification to that level could be made and an explanation as to why it could not.~~

(~~c~~ b) The designated person shall review and identify data trends for all sampling results. The designated person shall evaluate trends to determine if corrective action is needed. The results of the review shall be documented in the facility's SOPs and readily retrievable during inspection in accordance with the requirements in section 1738.9.

(~~d~~ c) Environmental sampling shall be done in compliance with the Controlled Environment Testing Association's (CETA's) Certification Application Guide USP <797> Viable Environmental Sampling & Gowning Evaluation (CAG-009, Revised October 2022), which is hereby incorporated by reference.

(~~e~~ d) Incubators ~~must~~ shall be cleaned, maintained, calibrated and operated in accordance with the manufacturer's specifications. Temperatures must be monitored either manually or by a continuous recording device during incubation, and the results must be reviewed and documented as described in the facility's SOPs. For incubators without specific manufacturers' specifications, cleaning shall take place at least every 30 days and calibration shall take place at least every 12 months.

Note: Authority cited: Sections 4005, 4008, and 4126.8, Business and Professions Code. Reference: Sections 4005, 4081, 4126.8, 4301, and 4306.5, Business and Professions Code.

1738.7. Cleaning and Disinfecting.

In addition to the requirements in USP Chapter 825, the processing of radiopharmaceuticals shall ~~comply~~ meet ~~with all of~~ the requirements of this section.

(a) Cleaning, disinfection, and sporicidal agents shall be used in accordance with manufacturers' specifications and shall occur at the minimum frequencies listed in Table 5 of USP Chapter 825. Incubators must be cleaned at least monthly.

(b) Reusable cleaning supplies, not for use in the PEC, shall not be stored within 1 meter of the PEC.

Note: Authority cited: Sections 4005, 4008, and 4126.8, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, and 4306.5, Business and Professions Code.

1738.8. Assigning BUD.

In addition to the requirements in USP Chapter 825, the processing of radiopharmaceuticals shall ~~comply~~ meet ~~with all of~~ the requirements of this section.

(a) A radiopharmaceutical's beyond-use date (BUD) shall not exceed the shortest BUD of any of its components.

(b) No radiopharmaceutical CSP shall be administered after the labeled BUD. A dose shall not be sent for a scheduled administration that would occur after the labeled BUD.

(c) Extension of a suggested use-by time of a conventionally manufactured kit shall not exceed the BUDs in Table 7 of USP Chapter 825, for the sterility of the preparation or product.

(d) Prior to the extension of a suggested use-by time for a conventionally manufactured kit, the pharmacy must maintain documentation of at least the following:

(1) Factors that necessitate its extension, including a full assessment of patient need for the extension.

(2) Evidence that supports that the extension maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate.

For the purposes of this section, the facility shall have SOPs that cover and are specific to each facility's location and kit.

Note: Authority cited: Sections 4005, 4008, and 4126.8, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, and 4306.5, Business and Professions Code.

1738.9. Documentation.

In addition to the requirements in USP Chapter 825, the processing of radiopharmaceuticals shall ~~comply~~ meet ~~with all of~~ the requirements of this section.

(a) A record of preparation must include a compounding record compliant with section 9.2 of USP Chapter 825.

(b) A record for preparation with minor deviations or a record of compounding shall be maintained and, upon request, be produced as a single document. The document shall satisfy the requirements of USP Chapter 825, as well as the following:

(1) The assigned internal identification number shall be unique for each preparation.
(2) The manufacturer, lot number, and expiration date shall be recorded for each component for radiopharmaceutical. Documenting the National Drug Code (NDC) alone does not meet this requirement.
(3) The total quantity compounded shall include the number of units made and either the volume or the weight of each unit.
(4) The identity of each person performing the compounding and pharmacist verifying the final drug preparation.
(5) When applicable, endotoxin level calculations and readings.

(c) Records required by USP Chapter 825 or this Article, shall be maintained in a readily retrievable form, for at least three years from the date the record was created or relied upon. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4081 and 4105.

(d) Records ~~created~~ shall be created and maintained in a manner to provide an audit trail for revisions and updates of each record document. Prior versions of each record must be maintained, for a least three years from the date the record was created**, modified** or relied upon, in a readily retrievable and easily readable, or rendered in an easily readable, format and include the changes to the document, identification of **the** individual who made the change, and the date of each change.

Note: Authority cited: Sections 4005, 4008, and 4126.8, Business and Professions Code. Reference: Sections 4005, 4081, 4105, 4126.8, 4301, and 4306.5, Business and Professions Code.

1738.10. Preparation.

In addition to the requirements in USP Chapter 825, the processing of radiopharmaceuticals shall ~~comply~~ meet ~~with all of~~ the requirements of this section.

(a) The individual responsible for preparing a nonsterile radiopharmaceutical shall:

(1) Follow manufacturer preparation instructions, unless minor deviations are made pursuant to subsection (c).
(2) Only use an area that is suitably cleaned and is uncluttered.
(3) Have documented processes in its SOPs for activities (e.g., cleaning) between the preparation cycles of different nonsterile products.

(b) The individual responsible for preparing a sterile radiopharmaceutical (including intravascular devices) shall:

(1) Follow manufacturer preparation instructions, unless minor deviations are made pursuant to subsection (c).
(2) Use at least the minimum environmental standards from section 7 of USP Chapter 825.

(c) When preparing radiopharmaceuticals with minor deviations ("preparation with minor deviations" as defined in USP Chapter 825)~~,~~ an SOP shall at least define the circumstances that necessitate**~~d the~~ d** deviation and all quality control testing requirements and limits. **~~Such circumstances shall, at a minimum, include patient need or facts that support the deviation that maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate in the professional judgment of the pharmacist.~~**

(d) Equipment and supplies initially used for processing of blood components (including red blood cells) shall be solely dedicated for processing of blood components. Equipment and supplies shall be thoroughly cleaned and disinfected, in accordance with section 1738.7, prior to initiation of the next radiolabeling procedure.

(e) When processing blood components, all garb must be removed and replaced prior to initiation of the next radiolabeling procedure.

Note: Authority cited: Sections 4005, 4008, and 4126.8, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, and 4306.5, Business and Professions Code.

1738.11. Compounding.

In addition to the requirements in USP Chapter 825, the processing of radiopharmaceuticals shall ~~comply~~ meet ~~with all of~~ the requirements of this section.

(a) All compounding of radiopharmaceuticals shall comply with all radioactive materials licensing requirements for appropriate radiation safety considerations issued by the California Department of Public Health pursuant to section 30190 of Title 17 of the California Code of Regulations, any other state licensing agency that issues specific radioactive materials licenses, or the United States Nuclear

Regulatory Commission pursuant to section 32.72 of title 10 of the Code of Federal Regulations, and utilize applicable environmental controls.

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

(c) Except for sterile radiopharmaceuticals made for inhalation or ophthalmic administration, prior to releasing a sterile radiopharmaceutical made from one or more nonsterile component(s), results of bacterial endotoxin testing shall be reviewed and recorded. Results shall be documented in the compounding record specified in Section 9.2 of USP Chapter 825.

Note: Authority cited: Sections 4005, 4008, and 4126.8, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, and 4306.5, Business and Professions Code.

1738.12. Dispensing.

In addition to the requirements in USP Chapter 825, the processing of radiopharmaceuticals shall ~~comply~~ meet ~~with all of~~ the requirements of this section.

All dispensed radiopharmaceutical doses shall be labeled with the information required by Business and Professions Code section 4076 and section 1707.5. Outer shielding labels shall contain the name and contact information of the dispensing pharmacy.

Note: Authority cited: Sections 4005, 4008, and 4126.8, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, and 4306.5, Business and Professions Code.

1738.13. Repackaging.

In addition to the requirements in USP Chapter 825, the processing of radiopharmaceuticals shall ~~comply~~ meet ~~with all of~~ the requirements of this section.

(a) The inner container of a repackaged radiopharmaceutical shall be labeled with the following:

(1) Standard radiation symbol.
(2) The words "Caution—Radioactive Material."

(3) The radionuclide and chemical form (generic name).
(4) Radioactivity with units at **the** time of calibration and the calibration time.

(b)The outer shielding of a repackaged radiopharmaceutical shall be labeled with the following:

(1) Standard radiation symbol.
(2) The words "Caution—Radioactive Material."
(3) The radionuclide and chemical form (generic name).
(4) Radioactivity with units at **the** time of calibration and the calibration time.
(5) Volume, or number of units (e.g., capsules), as applicable.
(6) Product expiration or BUD (consistent with Table 7 of USP Chapter 825), as applicable.
(7) Special storage and handling instructions.

Note: Authority cited: Sections 4005, 4008, and 4126.8, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, and 4306.5, Business and Professions Code.

1738.14. Quality Assurance and Quality Control

In addition to the standards established in USP Chapter 825, the processing of radiopharmaceuticals shall ~~comply~~ meet ~~with all of~~ the requirements of this section. The facility shall have SOPs that cover and are specific to each location and manufacturer.

(a) The quality assurance program shall comply with section 1711 and the standards contained in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. In addition, the program shall include a written procedure for any action(s) taken, in the event any radiopharmaceutical is discovered to be outside the expected standards for integrity, quality, and purity, such as a recall.

(b) The board shall be notified in writing within ~~**72**~~ **96 hours** of ~~a~~ the facility's receipt of a complaint, excluding delivery delays, involving a radiopharmaceutical. Recalls and adverse drug experiences as defined in 21 CFR **section** 310.305(b) ~~events~~ ~~**must**~~ **shall** be reported to the Board and other agencies in compliance with relevant provisions of law.

(c) In addition to subsection (b), **the pharmacist-in-charge shall initiate a review of any all** complaints made to the facility related to a potential quality problem with a radiopharmaceutical, and **any all** reported adverse drug experiences ~~**as defined in 21 CFR 310.305(b)**~~ ~~events shall be reviewed by the pharmacist-in-charge~~ within 72 hours of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs. In the event the PIC is not available within 72 hours, the PIC will define in the SOPs the pharmacist who will be required to review.

(d) The SOPs shall specify the steps to be taken if any classified area fails to meet the specified ISO classification, including the investigative and corrective actions, allowable activities, and retesting procedures. This subsection shall also include actions to be taken if the compounding area or equipment is rendered unusable or in downtime situation**s**.

(e) The SOPs shall be reviewed on an annual basis by the pharmacist-in-charge. Such review shall be documented by the pharmacist-in-charge consistent with the SOPs. The SOPs shall be updated to reflect changes to ~~compounding~~ processes, facility changes, or other changes that impact the ~~CSP~~radiopharmaceutical. Such SOP changes shall be disseminated to the affected staff prior to implementation. **Documentation of compliance with the subdivision shall be maintained for three years.**

(f) Failure to follow written SOPs constitutes a basis for enforcement action.

Note: Authority cited: Sections 4005, 4008, and 4126.8, Business and Professions Code. Reference: Sections 4005, 4126.8, 4126.9, 4127.1, 4301, and 4306.5, Business and Professions Code.