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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

XVI. Discussion and Possible Action to Make Changes in Response to Comments or to Adopt or Amend Proposed Text at Title 16 California Code of Regulations Sections 1735 e seq. and 1751 et seq. Relating to Pharmacy Compounding

At the October 2013 Board Meeting, the board moved to initial notice of proposed changes in the California's compounding regulations (located in 16 California Code of Regulations Sections 1735 et seq. and 1751 et seq). The 45 day comment period ran from November 29, 2013 – January 13, 2014. A regulation hearing was held on January 16, 2014 to provide the public with an opportunity to provide comments in another forum. At the January 2014 board meeting, the board made a motion to allow the sterile compounding workgroup to work through the comments received and submit a second version of the proposed text based on comments. At the April 2014 Board meeting, the Board voted to withdraw the current compounding rulemaking, revise the language to incorporate many of the comments submitted in response to the initial regulation notice and notice the new language as a new rulemaking.

At the July 2015 Board Meeting, the board moved to initial notice of proposed changes in the California's compounding regulations (located in 16 California Code of Regulations Sections 1735 et seq. and 1751 et seq). The 45 day comment period ran from September 5, 2014 – October 20, 2014. A regulation hearing was held on November 4, 2014 to provide the public with an opportunity to provide comments in another forum.

Attachment 1 contains the board's documents that are required to release a regulation for the 45 days of public comment – the notice, the initial statement of reasons and the proposed text. During the notice period, the board received many written comments. These written comments will available for review at the board meeting.

Attachment 2 is a compilation document of the written comments. Board Manager Lori Martinez sorted all written comments received by section number, so members can review all related comments together.

At this Meeting

The board will have the opportunity to discuss the regulation, the comments received and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation as initially noticed
2. Amend the regulation in some way(s) to address concerns expressed in the comments
3. Provide general guidance to the Enforcement and Compounding Committee to do more work on the regulation and bring it back to the board.

Attachment 1

Title 16. Board of Pharmacy

Proposed Language

To Amend § 1735 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735. Compounding in Licensed Pharmacies.

(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug

(2) Altering the strength of a drug

(3) Combining components or active ingredients

(4) Preparing a compounded drug ~~product~~ preparation from chemicals or bulk drug substances

(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal, topical, or injectable administration, nor does it include the sole act of tablet splitting or crushing, capsule opening, or the addition of flavoring agent(s) to enhance palatability.

(c) "Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug ~~product~~ preparation that is commercially available in the marketplace.

(d) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile ~~injectable~~ compounding are stated by Article 7 (Section 1751 et seq.).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.1 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.1. Compounding Definitions.

(a) "Ante-area" (also called ante-room) means an ISO Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate-generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the buffer area and maintains air flows from clean to dirty areas.

(b) "Batch" means compounding of two or more finished drug preparation units produced during the same continuous cycle of compounding and shall include any multiple dose vials prepared for administration to more than one patient.

(c) "Beyond use date" means the date or date and time after which a compounded drug preparation shall not be stored or transported, or administration begun.

(d) "Buffer area" means an area providing at least an ISO Class 7 or better air quality where the primary engineering control is physically located.

(e) "Bulk drug" means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.

(f) "Cleanroom" (which may also be referred to as a buffer area) means a physically separate room with walls and doors providing at least an ISO Class 7 or better air quality where the primary engineering control is physically located. This room maintains segregation from the adjacent ante-area (ante-room) by means of specific pressure differentials. For rooms providing a physical separation through the use of walls, doors, and pass-throughs, a minimum differential positive pressure of 0.02- to 0.05-inch water column is required. For buffer areas not physically separated from the ante-areas, the principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. Using

displacement airflow typically requires an air velocity of 40 ft per minute or more from the buffer area across the line of demarcation into the ante-area. The displacement concept shall not be used for high-risk compounding.

(g) "Controlled cold temperature" means 2.2 degrees to 7.7 degrees C (36 degrees to 46 degrees F).

(h) "Controlled freezer temperature" means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F).

(i) "Controlled room temperature" means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).

~~(a)~~ (j) "Equipment" means items that must be calibrated, maintained or periodically certified.

(k) "First air" means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

(l) "Gloved fingertip sampling" means a process where, compounding personnel lightly press each fingertip and thumb onto appropriate growth media, that are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganisms.

~~(b)~~ (m) "Integrity" means that all aspects of quality including sterility, packaging, chemical stability and potentcy, handling, and transport and storage are maintained throughout the drug preparation process, and ~~retention of potency~~ until the ~~expiration~~ beyond use date ~~noted~~ provided on the label.

(n) "Media-fill test" means a test that mimics compounding procedures using a growth-based media to demonstrate that aseptic technique of compounding personnel or processes routinely employed do not result in microbial contamination. Media fill tests are conducted on the most challenging and routine compounding procedures performed.

(o) "Parenteral" means a sterile preparation of drugs for injection or implantation through one or more layers of skin.

(p) "Personal protective equipment" means clothing or devices that protect the employee from exposure to drug products and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.

~~(c)~~ (q) "Potency" means active ingredient strength within +/- 10% (or the range specified in USP37-NF32, 37th Revision, Effective May 1, 2014) of the labeled amount.

(r) "Preparation" means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not contain sterile products.

(s) '"Prescriber's office" or "prescriber office" means an office or suite of offices in which a prescriber regularly sees patients for outpatient diagnosis and treatment.

(t) "Primary Engineering Control (PEC)" means a device that provides an ISO Class 5 environment or better through the use of unidirectional HEPA filtered first air.

(u) "Process validation" means demonstrating that when a process is operated within specified limits, the process will consistently produce prepartations complying with predetermined requirements. If any aspect of the process is changed, the process would need to be revalidated.

(v) "Product" means a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

~~(d)~~ (w) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active and inactive ingredients other than those noted on the label.

(x)"Segregated compounding area" means a designated space where a device that provides unidirectional airflow of ISO Class 5 air quality, including compounding aceptic isolators, is located within either a demarcated area (at least three foot perimeter) or room. Such area shall contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation, and shall not have a sink located within at least three feet of the ISO Class 5 PEC. This sterile compounding area will be restricted to preparing sterile-to-sterile compounded preparations.

(y) "Smoke test" means an analysis of the airflow in the ISO Class 5 PEC using a smoke generating device.

~~(e)~~ (z) "Strength" means amount of active ingredient per unit of a compounded drug ~~product~~ preparation.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.2 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.2. Compounding Limitations and Requirements; Self-Assessment.

(a) Except as specified in (b) and (c), no drug ~~product~~ preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug ~~product~~ preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug ~~product~~ preparations in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A "reasonable quantity" furnished to a prescriber for office use by the prescriber as authorized by ~~as used in~~ Business and Professions Code section 4052 subdivision (a)(1) means that amount of compounded drug ~~product~~ preparation that:

(1) is ordered and paid for by the prescriber, using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for either office administration ~~or application to patients in the prescriber's office, or for distribution of not more than~~ or furnishing of a 72-hour supply ~~to the prescriber's patients, as estimated by the prescriber~~; and

(2) is delivered to the prescriber office and signed for by the prescriber; and

(3) is sufficient for administration or application to patients solely in the prescriber's office, or for furnishing of not more than a 72-hour supply solely to the prescriber's own patients seen as part of regular treatment in the prescriber's office, as estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy; and

(4) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and

~~(3)~~ (5) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug ~~product~~ preparation; and

(6) does not exceed an amount the pharmacy can reasonably and safely compound.

(d) No pharmacy or pharmacist shall compound a drug preparation that:

(1) is classified by the FDA as demonstrably difficult to compound;

(2) appears on a FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective; or

(3) is a copy or essentially a copy of one or more drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense. The pharmacy shall retain a copy of the documentation of the shortage in the pharmacy records for three years.

(~~d~~ e) A drug ~~product~~ preparation shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) ~~Expiration dating requirements.~~ The rationale or reference source for determining the maximum allowable beyond use date for this preparation.

(4) Inactive ingredients to be used.

(5) ~~Process and/or~~ Specific compounding steps ~~procedure~~ used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(~~e~~ f) Where a pharmacy does not routinely compound a particular drug ~~product~~ preparation, the master formula record for that ~~product~~ preparation may be recorded on the prescription document itself.

(~~f~~ g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug ~~product~~ preparation until it is dispensed.

(~~g~~ h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia~~l~~ and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

(~~h~~ i) Every compounded drug ~~product~~ preparation shall be given a~~n expiration~~ beyond use date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used, stored, transported, or administration begun. This "beyond use date" of the compounded drug ~~product~~ preparation shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug ~~product~~ preparation, unless a longer date is supported by stability studies of finished drugs or compounded drug ~~products~~ preparations using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(~~i~~ j) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug ~~product~~ preparation.

(~~j~~ k) Prior to allowing any drug ~~product~~ preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. ~~(Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.)~~ That form contains a first section applicable to all compounding, and a second section applicable to sterile ~~injectable~~ compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the

pharmacist-in-charge before any sterile ~~injectable~~ compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(l) Packages of ingredients that lack a supplier's expiration date are subject to the following limitations:

(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy unless either appropriate documented inspection or analytical testing indicates that the ingredient has retained its purity and quality for use in compounded drug preparations, considering the container in which it is packaged and the storage conditions, and

(2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy, unless either appropriate and documented inspection or analytical testing indicates that the ingredient has retained its purity.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code, Sections 1735, 1735.1, 1735.8, and 1751.1-1751.8 of Title 16, Division 17, of the California Code of Regulations.

To Amend § 1735.3 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.3. ~~Records~~ Recordkeeping ~~of~~ for Compounded Drug ~~Products~~ Preparations.

(a) For each compounded drug ~~product~~ preparation, ~~the~~ pharmacy records shall include:

(1) The master formula record.

(2) The date the drug ~~product~~ preparation was compounded.

(3) The identity of ~~the~~ any pharmacy personnel ~~who compounded the~~ engaged in compounding the drug ~~product~~ preparation.

(4) The identity of the pharmacist reviewing the final drug ~~product~~ preparation.

(5) The quantity of each component used in compounding the drug ~~product~~ preparation.

(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile ~~products~~ preparations compounded on a one-time basis for administration within seventy-two (72) hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) (~~35~~ 37th Revision, Effective May 1, ~~2012~~ 2014), hereby incorporated by reference~~, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code~~.

(7) A pharmacy-assigned reference or lot number for the compounded drug ~~product~~ preparation.

(8) The ~~expiration~~ beyond use date of the final compounded drug ~~product~~ preparation.

(9) The final quantity or amount of drug ~~product~~ preparation compounded for dispensing.

(10) Storage preparation for the drug preparation.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Active pharmaceutical ingredients shall be obtained from a FDA registered supplier. All other ~~C~~chemicals, bulk drug substances, and drug products~~, and components~~ used to compound drug ~~products~~ preparations shall be obtained, whenever possible, from ~~reliable~~ FDA-registered suppliers. The pharmacy shall acquire and retain ~~any available~~ certificates of purity or analysis for chemicals, and bulk drug substances~~, drug products, and components~~ used in compounding. ~~Certificate s of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.~~ Certificates of purity or analysis are to be matched to the product received.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created. 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 subsection (c).

Authority cited: Sections 4005, 4127, and 4169, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.4 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.4. Labeling of Compounded Drug ~~Products~~ Preparations.

(a) In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug ~~product~~ preparation shall contain the generic name(s) of the principal active ingredient(s).

(b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.

(c) Drug ~~products~~ preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy reference or lot number, and ~~expiration~~ beyond use date.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

To Amend § 1735.5 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.5. Compounding Policies and Procedures.

(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance,

operation, and other standard operating procedures related to compounding. The pharmacy shall follow its policies and procedures and failure to follow these policies and procedures shall constitute grounds for disciplinary action.

(b) The policy and procedure manual shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

(c) The policy and procedure manual shall include the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.

(2) Evidence that staff have been educated and trained on all policies and procedures.

(~~2~~ 3) ~~Documentation of a~~ A written plan for recall of a dispensed compounded drug ~~product~~ preparation where subsequent verification demonstrates the potential for adverse effects with continued use ~~of a compounded drug product~~. All affected doses can be accounted for as part of the recall.

(~~3~~ 4) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(5) The procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(~~4~~ 6) Documentation of the methodology appropriate to compounded drug preparations used to ~~test~~ validate integrity, potency, quality, and labeled strength of compounded drug ~~products~~ preparations.

(~~5~~ 7) Documentation of the methodology used to determine appropriate ~~expiration~~ beyond use dates for compounded drug ~~products~~ preparations.

(8) Dates of annual reviews of the policy and procedure manual by the pharmacist-in-charge, signed and dated by the pharmacist-in-charge.

(9) Dates of any revisions to the policy and procedure manual approved by the pharmacist-in-charge, signed and dated by the pharmacist-in-charge.

(10) Policies and procedures for storage of compounded sterile drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures.
(11) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, ~~and~~ 4127, and 4301, Business and Professions Code.

To Amend § 1735.6 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.6. Compounding Facilities and Equipment.

(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug ~~products~~ preparations. Where applicable, this shall include records of certification(s) of facilities or equipment.
(b) Any equipment used to compound drug ~~products~~ preparations shall be stored, used, and maintained in accordance with manufacturers' specifications.
(c) Any equipment that weighs, measures, or transfers ingredients used to compound drug ~~products~~ preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, per manufacturer's specifications, to ensure accuracy. Documentation of each such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1735.7 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.7. Training of Compounding Staff.

(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.
(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.
(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug ~~product~~ preparation.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1735.8 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.8. Compounding Quality Assurance.

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug ~~products~~ preparations.
(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.
(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug ~~products~~

preparations. All qualitative and quantitative analysis reports for compounded drug ~~products~~ preparations shall be retained by the pharmacy and collated with the compounding record and master formula.

(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug ~~product~~ preparation is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.

(e) The quality assurance plan shall include a written procedure for responding to out-of-range temperature variations, including for preparations furnished to patient care areas.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1751 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 7. Sterile ~~Injectable~~ Compounding

1751. Sterile ~~Injectable~~ Compounding; Compounding Area; Self-Assessment.

(a) Any pharmacy engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile ~~injectable~~ compounding.

(b) Any pharmacy compounding sterile ~~injectable~~ drug ~~products~~ preparations shall have a ~~designated~~ compounding area designated for the preparation of sterile ~~injectable~~ drug ~~products~~preparations that is in a restricted location where traffic has no impact on the performance of the PEC(s). The buffer area, including the walls, ceilings, and floors, shall be constructed in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. The pharmacy shall be ventilated in a manner in accordance with Section

505.12 of Title 24, Part 4, Chapter 5 of the California Code of Regulations. ~~which shall meet the following standards:~~ The environments within the pharmacy shall meet the following standards:

(1) ~~Clean Room and Work Station Requirements, shall be in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~

~~(2) Walls, ceilings and floors shall be constructed in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~

~~(3) Be ventilated in a manner in accordance with Section 505.12 of Title 24, Chapter 5 of the California Code of Regulations.~~

~~(4) Be~~ Each ISO environment shall be certified ~~annually~~ at least every six months by a qualified technician ~~who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration~~ in accordance with Section 1751.4 of Title 16, Division 17, of the California Code of Regulations. Certification records must be retained for at least 3 years.

~~(5)~~ (2) ~~The pharmacy shall be arranged in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~ Items related to the compounding of sterile ~~injectable~~ drug ~~products~~ preparations within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.

~~(6)~~ (3) A sink shall be included in accordance with Section 1250 of Title 24, Part 2, of the California Code of Regulations. Sinks and drains shall not be present in an ISO Class 7 or better buffer area, nor within three feet of an ISO Class 5 PEC or better located in segregated compounding areas. A sink may be located in an ante-area.

~~(7)~~ (4)There shall be a refrigerator and~~, /or~~ where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing.

(c) Any pharmacy compounding a sterile ~~injectable~~ drug ~~product~~ preparation from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4127 and 4127.7, Business and Professions Code; Sections

1735, 1735.1,-1735.8., and 1751.1-1751.8. of Title 16, Division 17, of the California Code of Regulations; and Section 18944, Health and Safety Code.

To Amend § 1751.1 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.1. Sterile ~~Injectable~~ Compounding Recordkeeping Requirements.

(a) ~~Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.~~

~~(b)~~ In addition to the records required by section 1735.3 ~~and subdivision (a)~~, for sterile compounded drug ~~products~~ preparation ~~compounded from one or more non-sterile ingredients~~, the following records must be made and kept by the pharmacy:

(1) The training and competency evaluation of employees in sterile ~~product~~ preparation procedures.

(2) Results of hand hygiene and garbing assessment with integrated gloved fingertip testing.

(3) Results of assessments of personnel for aseptic techniques including results of media fill tests and gloved fingertip testing performed in association with media fill testing.

(4) Results of viable volumetric air and surface sampling.

~~(2)~~ (5) Daily documentation of room, ~~R~~ refrigerator, and freezer temperatures appropriate for drug preparations consistent with the temperatures listed in section 1735.1 for:~~.~~

(A) Controlled room temperature.

(B) Controlled cold temperature.

(C) Controlled freezer temperature.

~~(3)~~ (6) Certification(s) of the sterile compounding environment.

(7) Daily documentation of air pressure differentials or air velocity between adjoining all ISO rooms or areas and measurement between all ISO rooms or areas, including those associated with compounding aseptic (containment) isolators.

~~(4)~~ (8) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).

~~(5)~~ (9) Logs or other documentation of ~~inspection~~s for expired or recalled pharmaceutical products or raw ingredients.

~~(6)~~ (10) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

(b) Pharmacies compounding sterile drug preparations for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name of the compounded drug preparation, lot number, amount, and date on which the preparation was provided to a prescriber.

(c) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created. 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 subsection (c).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.2 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.2. Sterile ~~Injectable~~ Compounding Labeling Requirements.

In addition to the labeling information required under Business and Professions Code section 4076 and California Code of Regulations section 1735.4, a pharmacy which compounds sterile ~~injectable~~ drug ~~products~~ preparations shall include the following information on the labels for those ~~products~~ preparations:

(a) Telephone number of the pharmacy, except for sterile ~~injectable~~ drug ~~products~~ preparations dispensed ~~for~~ to inpatients ~~of~~ by a hospital pharmacy.

(b) Name and concentrations of ingredients contained in the sterile injectable drug product preparation.

(c) Instructions for storage and handling.

(d) All cytotoxic hazardous agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "Cytotoxic Hazardous – Dispose of Properly." or "Chemotherapy - Dispose of Properly," if applicable.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

To Amend § 1751.3 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.3. Sterile Injectable Compounding Policies and Procedures.

(a) Any pharmacy engaged in compounding sterile injectable drug products preparations shall maintain a written policy and procedure manual for compounding that includes, in addition to the elements required by section 1735.5, written policies and procedures regarding the following:

(1) Compounding, filling, and labeling of sterile injectable compounds drug preparations.

(2) Labeling of the sterile injectable drug product preparations based on the intended route of administration and recommended rate of administration.

(3) Proper use of Eequipment and supplies.

(4) Training of staff in all aspects of the preparation of sterile injectable drug products preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; cleaning and disinfection of controlled compounding areas and proper aseptic technique.

(5) Hand hygiene and garbing.

(6) Cleaning and maintenance of ISO environments and segregated compounding areas.

(7) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.

(8) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.

(9) Media fill testing procedure.

(10) Compounded sterile drug preparation stability and beyond use dating.

(11) Visual inspection and other final quality checks of sterile drug preparations.

~~(5)~~ (12) Procedures for handling, compounding and disposal of ~~cytotoxic~~ hazardous agents.

~~(6)~~ (13) Quality assurance program.

~~(7)~~ (14) Record keeping requirements.

(b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.

(c) Pharmacies compounding sterile ~~injectable~~ drug ~~products~~ preparations shall have written policies and procedures for the disposal of infectious materials and/or materials containing ~~cytotoxic~~ hazardous residues. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(d) Pharmacies compounding sterile ~~injectable~~ drug ~~products~~ preparations ~~from one or more non-sterile ingredients~~ must have written policies and procedures that comply with the following:

(1) All written policies and procedures shall be immediately available to all personnel involved in these activities and board inspectors.

(2) All personnel involved must read the policies and procedures before compounding sterile ~~injectable~~ drug ~~products~~ preparations, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.

(3) Policies and procedures must address at least the following:

(A) Orientation, training, and ~~C~~competency evaluation of compounding personnel.

(B) Storage and handling of products and supplies.

(C) Storage and delivery of final products.

(D) Media fill testing and ~~P~~process validation.

(E) ~~Personnel access and movement of materials into and near the controlled area~~ Conduct of personnel in controlled areas and aseptic technique overview.

(F) Use and maintenance of ~~environmental control devices~~ PECs used to create the ~~critical~~ direct compounding area for ~~manipulation of sterile products~~ compounding of sterile drug preparations ~~(e.g., laminar airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations)~~.

(G) ~~Regular~~ Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area ~~and the alternation of disinfectants~~ as specified in section 1751.4. ~~Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.~~

(H) ~~Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.~~ Non-viable particle testing.

(I) ~~For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.~~ Viable air sampling.

(J) ~~Sterilization.~~ Surface sampling.

(K) ~~End-product evaluation and testing.~~ Airflow considerations and pressure differential monitoring.

(L) Temperature and humidity monitoring in compounding and controlled storage areas.

(M) Facility management including certification and prevention maintenance of controlled environments and related equipment.

(N) Gloved fingertip sampling.

(O) Compounded sterile product stability and assignment of beyond use dating

(P) Use of automated compounding devices (if applicable).

(Q) Hazardous drug compounding (if applicable).

(i) Hazardous drug employee training and safety program.

(ii) Hazardous drug handling, storage, labeling and transport.

(iii) Hazardous drug compounding techniques.

(iv) Hazardous drug spill, deactivation and waste management.

(R) Preparing sterile solutions from nonsterile components (if applicable).

(S) Hand hygiene and garbing.

(4) Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subparagraph.

(A) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.

(B) For sterile batch compounding:,

(i) use of master formulas and compounding work sheets;

(ii) appropriate documentation; and

(iii) appropriate sterility and bacterial endotoxin testing.

(C) For non-sterile to sterile compounding:

(i) Sterilization methods

(ii) End-product evaluation and testing.

(D) Action levels for colony-forming units (CFUs) detected during viable surface testing, glove fingertip and volumetric air sampling.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.4 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.4. Facility and Equipment Standards for Sterile ~~Injectable~~ Compounding.

(a) No sterile ~~injectable~~ drug ~~product~~ preparation shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile ~~injectable~~ drug ~~products~~ preparations.

(b) During the compounding of preparation of sterile ~~injectable~~ drug ~~products~~ preparations, access to the areas designated ~~area or cleanroom~~ for compounding must be limited to those individuals who are properly attired.

(c) All equipment used in the areas designated ~~area or cleanroom~~ for compounding must be made of a material that can be easily cleaned and disinfected.

(d) Cleaning and disinfecting surfaces in the ISO Class 5 PEC shall occur frequently, including:

(1) at the beginning of each shift;

(2) before and after each batch;

(3) after each spill; and

(4) when surface contamination is known or suspected.

~~(d)~~ (e) ~~Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.~~ Counters, cleanable work surfaces and floors shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent (e.g., sterile isopropyl alcohol) daily. Walls, ceilings, storage shelving, tables and stools shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent (e.g., sterile isopropyl alcohol) monthly. Cleaning and disinfecting shall occur after any unanticipated event that could increase the risk of contamination.

~~(e)~~ (f) Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilties (CAG-003-2006-11, Revised January 31, 2012). Certification records must be retained for at least 3 years. Compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 buffer area if the isolator meets the following criteria:

(1) particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.

(2) not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.

(3) recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

Compounding aseptic isolators or compounding aseptic containment isolators that do not meet the requirements as outlined in this subdivision and are not located within an ISO Class 7 buffer area may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

(g) Pharmacies preparing ~~parenteral~~ sterile ~~cytotoxic~~ hazardous agents shall do so in accordance with Section 505.12.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a ~~laminar air flow hood~~ negative pressure PEC. The ~~hood~~ negative pressure PEC must be certified ~~annually~~ every six months by a qualified technician who is familiar with ~~the methods and procedures for certifying laminar air flow hoods and cleanroom requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications.~~ CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-11, Revised January 31, 2012). ~~Certification records must be retained for at least 3 years.~~ Any drug preparation that is compounded in a hazardous drug PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous.

During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occu, complete with hair cover, facemask, beard cover (if applicable), polyprophylen or low shedding gown that closes in the

back, shoe covers, and two layers of gloves that have been tested to meet ASTM 6978-05 with the outermost glove that contacts the sterile drug preparation.

(h) If a compounding aseptic isolator is certified by the manufacturer to maintain ISO Class 5 air quality during dynamic operation conditions during compounding as well as during the transfer of ingredients into and out of the compounding aseptic isolator, then it may be placed into a non-ISO classified room. Individuals that use compounding aseptic isolators in this manner must ensure appropriate garbing, which consists of donning sterile gloves over the isolator gloves immediately before non-hazardous compounding. These sterile gloves must be changed by each individual whenever continuous compounding is ceased and before compounding starts again.

(i) Viable surface sampling shall be done at least monthly for low and medium risk-level compounding and weekly for high-risk compounding. Volumetric air sampling by impaction shall be done at least once every six months for low and medium risk-level compounding and weekly for high-risk compounding. Viable surface and volumetric air sampling shall be performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling. Viable air sampling is to be performed under dynamic conditions that simulate actual production. Surface sampling is to be performed under dynamic conditions of actual compounding. When the environmental monitoring action levels are exceeded, the pharmacy shall identify the CFUs at least to the genus level in addition to conducting an investigation. Remediation shall include an immediate investigation of cleaning and compounding operations and facility management.

(j) The pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20 degrees Celsius (68 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb. Humidity levels should be consistent ASHRAE Standard 55 (30-65% RH).

Note: Authority Cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code; and Section 18944, Health and Safety Code.

To Amend § 1751.5 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.5. Sterile ~~Injectable~~ Compounding Attire.

~~(a) When preparing cytotoxic agents, gowns and gloves shall be worn.~~

~~(b)~~ (a) When compounding sterile drug ~~products~~ preparations ~~from one or more non-sterile ingredients~~ the following standards must be met:

(1) ~~Cleanroom garb~~ Personal protective equipment consisting of a ~~low~~ non-shedding ~~coverall~~ gown, head cover, face mask, facial hair covers (if applicable), and shoe covers must be worn inside the designated area at all times, unless the compounding aseptic isolator or compounding aseptic containment isolator manufacturer can provide written documentation, based on validated environmental testing, that any component of the personal protective equipment or personnel cleansing are not required .

(2) ~~Cleanroom garb~~ Personal protective equipment must be donned and removed in an ante-area or ~~outside the designated area~~ immediately outside the segregated compounding area.

(3) Personnel shall don personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. The following order is to be followed unless the pharmacy has a procedure in place that documents a method equivalent to or superior to the method described here: The donning of shoe covers or dedicated shoes, head and facial hair covers and face masks shall be followed by the washing of hands and forearms up to the elbows for 30 seconds with soap and water, drying hands, and then the donning of a non-shedding gown.

~~(3)~~ (4) Compounding personnel shall not wear ~~H~~hand, finger, ~~and~~ or wrist jewelry ~~must be eliminated~~. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.

~~(4) Head and facial hair must be kept out of the critical area or be covered.~~

(5) ~~Gloves made of low-shedding materials are required.~~ Sterile gloves that have been tested for compatibility with disinfection with isopropyl alcohol are required. Hand cleansing with a

persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or buffer area. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.

(6) Individuals experiencing rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections, or those wearing cosmetics shall be excluded from the compounding areas until their conditions are remedied.

~~(c) The requirements of subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.~~

(b) When preparing hazardous agents, appropriate gowns and personal protective equipment shall be worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.6 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.6 ~~Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.~~ Sterile Compounding Consultation; Training of Sterile Compounding Staff.

(a) Consultation shall be available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of sterile ~~injectable~~ drug ~~products~~ preparations and related supplies furnished by the pharmacy.

(b) The pharmacist-in-charge shall ~~be responsible to~~ ensure that all pharmacy personnel engaging in compounding sterile ~~injectable~~ drug ~~products~~ preparations ~~shall~~ have training and demonstrated competence in the safe handling and compounding of sterile ~~injectable~~ drug

~~products~~ preparations, including ~~cytotoxic~~ hazardous agents if the pharmacy compounds products with ~~cytotoxic~~ hazardous agents.

(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.

(d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations.

(e) Pharmacies that compound sterile ~~products from one or more non-sterile ingredients~~ preparations must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

(A) Aseptic technique.

(B) Pharmaceutical calculations and terminology.

(C) Sterile ~~product~~ preparation compounding documentation.

(D) Quality assurance procedures.

(E) Aseptic preparation procedures using media fill tests which are as complicated as the most complex manipulations performed by staff and which contain the same amount of volume transferred during the selected manipulations.

(F) Proper hand hygiene, gowning and gloving technique.

(G) General conduct in the controlled area.

(H) Cleaning, sanitizing, and maintaining of the equipment and ~~used in~~ the controlled area.

(I) Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients.

(J) Container, equipment, and closure system selection.

(2) Each person ~~assigned to the controlled area~~ engaged in sterile compounding must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency

and continuing training needs must be reassessed at least every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.7 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.7. Sterile ~~Injectable~~ Compounding Quality Assurance and Process Validation.

(a) Any pharmacy engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The ~~Q~~quality ~~A~~assurance ~~P~~program shall include at least the following:

(1) Procedures for ~~C~~cleaning and sanitization of the ~~parenteral~~ ~~medication~~ sterile preparation area.

~~(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.~~

~~(3)~~ (2) Actions to be taken in the event of a drug recall.

~~(4)~~ (3) ~~Written justification of~~ Documentation justifying the chosen ~~expiration~~ beyond use dates for compounded sterile ~~injectable~~ drug ~~products~~ preparations.

(b) Each individual involved in the preparation of sterile ~~injectable~~ drug ~~products~~ preparations must first successfully demonstrate competency by successfully performing aspect media fill tests ~~complete a validation process on technique~~ before being allowed to prepare sterile ~~injectable~~ drug ~~products~~ preparations. ~~The validation process shall be carried out in the same~~

~~manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare.~~ The media fill testing process shall be as complicated as the most complex manipulations performed by staff and contain the same amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be involved. Media used must have demonstrated the ability to support and promoted growth. Completed ~~medium~~ media samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then the employee's sterile preparation process must be evaluated, corrective action taken and documented, and the ~~validation process~~ media fill testing repeated. Personnel competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile products from non-sterile ingredients, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile ~~injectable~~ drug ~~products~~ preparations ~~is~~ are repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.

(c) All compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, all compounding personnel must successfully complete a gloved fingertip sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug ~~products~~ preparations.

(d) Re-evaluation of garbing and gloving competency shall occur at least every 12 months for personnel compounding products made from sterile ingredients and at least every six months for personnel compounding products from non-sterile ingredients.

~~(c)~~ (e) Batch-produced sterile ~~injectable~~ drug ~~products~~ preparations compounded from one or more non-sterile ingredients ~~shall be subject to documented end product testing for sterility~~ that are exposed longer than 12 hours at 2 to 8 degrees C and longer than 6 hours at warmer than 8 degrees C before they are sterilized shall meet the sterility test in accordance with

methodologies and processes found in Chapter 71 of the United States Pharmacopeia – National Formulary (USP37-NF32) (37th Revision, Effective May 1, 2015), and testing for pyrogens in accordance with the methods of Chapters 85 and 151 of the United States Pharmacopeia – National Formulary (USP37-NF32) (376th Revision, Effective May 1, 2014), hereby incorporated by reference, and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile.

In a circumstance where a batch-produced sterile drug preparation compounded from one or more non-sterile ingredients is necessary for immediate dispensing where failure to dispense could result in loss of life or intense suffering, the drug preparation may be dispensed before receipt of test results so long as the pharmacy complies with a written procedure included in the pharmacy's policies and procedures that includes:

(1) Prior to dispensing:

(A) Notifying the prescriber of the inability to conduct testing;

(B) Suggesting an available alternative product to the prescriber; and

(C) Securing the prescriber's written consent to dispense.

(2) And subsequent to dispensing:

(A) Daily observation of the incubating test specimens; and

(B) Immediate recall of the dispensed compounded sterile preparation's when there is any evidence of microbial or pyrogen growth in the test specimens.

Any such dispensing shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.

~~(d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.8 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.8. Beyond Use Dating for Sterile Compounded Drug Preparations.

In addition to the requirements and limitations of section 1735.2, subdivision (h), every sterile compounded drug preparation shall be given and labeled with a beyond use date that conforms to the following limitations, except that the beyond use date shall not exceed any expiration date or beyond use date provided by the manufacturer for any component in the preparation.

(a) Where the sterile compounded drug preparation was compounded solely with aseptic manipulations

(1) entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area with an ante-area, using only sterile ingredients, products, components, and devices; and

(2) the compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; and

(3) compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing

in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP36-NF31 through 1st Supplement) (36th Revision, Effective August 1, 2013), hereby incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed the following: 48 hours at controlled room

temperature; 14 days at controlled cold temperature; and 45 days at controlled freezer temperature.

(b) Where the sterile compounded drug preparation was compounded solely with aseptic manipulations

(1) entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area with an ante-area, using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and

(2) the compounding process involves complex aseptic manipulations other than the single-volume transfer; and

(3) the compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing

in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP36-NF31 through 1st Supplement) (36th Revision, Effective August 1, 2013), hereby incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed the following: 30 hours at controlled room temperature; 9 days at controlled cold temperature; and 45 days at controlled freezer temperature.

(c) Where the sterile compounded drug preparation was compounded solely with aseptic manipulations entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area with an ante-area, using non-sterile ingredients, including manufactured preparations not intended for sterile routes of administration, or non-sterile devices, before terminal sterilization, or where the sterile compounded drug preparation lacks effective antimicrobial preservatives, in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP36-NF31 through 1st Supplement) (36th Revision, Effective August 1, 2013), hereby incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage

and exposure periods cannot exceed the following: 24 hours at controlled room temperature; 3 days at controlled cold temperature; and 45 days at controlled freezer temperature.

For the purposes of this paragraph, "non-sterile" includes sterile contents of commercially manufactured preparations, sterile surfaces of devices, and containers for the preparation, transfer, sterilization, and packaging of compounded sterile preparations, that are exposed to worse than ISO Class 5 air quality for more than one hour.

(d) Where the sterile compounded drug preparation was compounded solely with aseptic manipulations

(1) entirely within an ISO Class 5 PEC that is located in a segregated compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed; and

(2) the compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer's original containers; and

(3) the compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device

in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP36-NF31 through 1st Supplement) (36th Revision, Effective August 1, 2013) hereby incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed 12 hours in a laminar air flow workbench or biological safety cabinet.

(e) Where the sterile compounded drug preparation was compounded

(1) using or containing hazardous drugs or components; and

(2) in facilities that prepare a low volume of hazardous drugs, where low volume is defined as five or less per a week, the use of two tiers of containment (e.g., closed system transfer device within a biological safety cabinet or compounding aseptic containment isolator that is located in a non-negative pressure room)

the beyond use date shall specify that storage and exposure periods cannot exceed 12 hours.

(f) Where any sterile compounded drug preparation was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (e), the sterile compounded drug preparation shall be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process. Unless the "immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. This provision does not preclude the use of a PEC to compound an "immediate use" preparation.

Such "immediate use" preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Add § 1751.9 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.9 Single-Dose and Multi-Dose Containers; Limitations on Use

(a) Single-dose ampules are for immediate use only, and once opened shall not be stored for any time period.

(b) Unless otherwise specified by the manufacturer, any single-dose container of a compounded sterile drug preparation other than an ampule, such as a bag, bottle, syringe or vial, shall be used in its entirety or its remaining contents discarded within the following time limit, depending on the environment:

(1) When needle-punctured in an environment with air quality worse than ISO Class 5, within one (1) hour;

(2) When needle-punctured in an environment with ISO Class 5 or better air quality, within six (6) hours.

(c) Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications shall be used in its entirety or its remaining contents discarded within twenty eight (28) days from initial opening or puncture. Any multi-dose container not stored according to the manufacturer's specifications shall be discarded immediately upon identification of such condition.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.10 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.8.~~ 1751.10. Sterile ~~Injectable~~ Compounding Reference Materials.

In any pharmacy engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations, there shall be current and appropriate reference materials regarding the compounding of sterile ~~injectable~~ drug ~~products~~ preparations located in or immediately available to the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Add Article 7.5 of Division 17 of Title 16 of the California Code of Regulations to read as follow

Article 7.5 Furnishing for Home Administration

To Amend § 1751.10 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.10.~~ **1752. Furnishing to Parenteral Patient at Home.**

Subject to all provisions of this article, a pharmacist may carry and furnish to a patient at home dangerous drugs, other than controlled substances, and devices for parenteral therapy when the dangerous drug or device is one currently prescribed for the patient.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

To Amend § 1751.11 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.11.~~ **1753. Furnishing to Home Health Agencies and Licensed Hospices.**

Subject to the following conditions, a licensed pharmacy may furnish to a home health agency licensed under provisions of Chapter 8 (commencing with section 1725 of Division 2 of the Health and Safety Code) or to a hospice licensed under provisions of Chapter 8.5 (commencing with section 1745 of Division 2 of the Health and Safety Code) dangerous drugs for parenteral therapy other than controlled substances, in a portable container for furnishing to patients at home for emergency treatment or adjustment of parenteral drug therapy by the home health agency or licensed hospice.

(a) The pharmacy, having ownership and responsibility for the portable containers, shall ensure that each portable container is:

(1) furnished by a registered pharmacist;

(2) sealed in such a manner that a tamper-proof seal must be broken to gain access to the drugs;

(3) under the effective control of a registered nurse, pharmacist or delivery person at all times when not in the pharmacy;

(4) labeled on the outside of the container with a list of the contents;

(5) maintained at an appropriate temperature according to United States Pharmacopeia Standards (1995, 23rd Revision), and protected at all times from extreme temperatures that could damage the contents.

(b) The portable container may contain up to:

(1) 1000mL of 0.9% sodium chloride intravenous infusion in containers of a size determined by the pharmacy;

(2) 1000mL of 5% dextrose in water injection in containers of a size determined by the pharmacy;

(3) two vials of urokinase 5000 units;

(4) Each of the following items shall be in sealed, unused containers; the furnishing pharmacy may select any or all of these dangerous drugs in up to five dosage units for inclusion in the sealed, portable container:

(A) heparin sodium lock flush 100 units/mL;

(B) heparin sodium lock flush 10 units/mL;

(C) epinephrine HCl solution 1:1000;

(D) epinephrine HCl solution 1:10,000;

(E) diphenhydramine HCl 50mg/mL;

(F) methylprednisolone 125mg/2mL;

(G) normal saline, preserved, up to 30 mL vials;

(H) naloxone 1mg/mL 2 mL;

(I) droperidol 5mg/2mL;

(J) prochlorperazine 10mg/2mL;

(K) promethazine 25mg/mL;

(L) dextrose 25gms/50mL;

(M) glucagon 1mg/mL;

(N) insulin (human) 100 units/mL;

(O) bumetamide 0.5mg/2mL;

(P) furosemide 10mg/mL;

(Q) EMLA Cream 5 gm tube;

(R) Lidocaine 1 percent 30mL vials.

(5) The pharmacy shall ensure that the specific dangerous drugs and quantities to be included in the portable container are listed in the home health agency's or licensed hospice's policy and procedures.

(c) The pharmacy shall not supply a portable container to a home health agency or licensed hospice which does not:

(1) implement and maintain policies and procedures for:

(A) the storage, temperature stability and transportation of the portable container;

(B) the furnishing of dangerous drugs from the portable container upon the written or oral authorization of a prescriber; and

(C) a specific treatment protocol for the administration of each medication contained in the portable container.

(2) have the policies, procedures and protocols reviewed and revised (as needed) annually by a group of professional personnel including a physician and surgeon, a pharmacist and a registered nurse.

(d) A copy of these policies, procedures and protocols shall be maintained by the furnishing pharmacy from each home health agency or licensed hospice for which the pharmacy furnishes portable containers.

(e) In cases where a drug has been administered to a patient pursuant to the oral order of a licensed prescriber, the pharmacy shall ensure that the oral order is immediately written down by the registered nurse or pharmacist and communicated by copy or fax within 24 hours to the

furnishing pharmacy, with a copy of the prescriber-signed document forwarded to the dispensing pharmacy within 20 days.

(f) The pharmacy shall ensure that within seven days (168 hours) after the seal has been broken on the portable container, the home health agency's director of nursing service or a registered nurse employed by the home health agency or licensed hospice returns the container to the furnishing pharmacy. The furnishing pharmacy shall then perform an inventory of the drugs used from the container, and if the container will be reused, must restock and reseal the container before it is again furnished to the home health agency or licensed hospice.

(g) The furnishing pharmacy shall have written policies and procedures for the contents, packaging, inventory monitoring, labeling and storage instructions of the portable container.

(h) The furnishing pharmacy shall ensure that the home health agency or licensed hospice returns the portable containers to the furnishing pharmacy at least every 60 days for verification of product quality, quantity, integrity and expiration dates, or within seven days (168 hours) after the seal has been broken.

(i) The furnishing pharmacy shall maintain a current inventory and record of all items placed into and furnished from the portable container.

Note: Authority cited: Sections 4005 and ~~and~~ 4057, Business and Professions Code. Reference: Sections 4040, 4057, 4081 and 4332, Business and Professions Code.

To Amend § 1751.12 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.12~~ 1754. Obligations of a Pharmacy Furnishing Portable Containers.

(a) A licensed pharmacy shall not issue portable containers to any home health agency or licensed hospice unless the home health agency or licensed hospice complies with provisions of section 1751.11.

(b) A licensed pharmacy shall cease to furnish portable containers to a home health agency or licensed hospice if the home health agency or licensed hospice does not comply with provisions of section 1751.11.

Note: Authority cited: Sections 4005 and 4057, Business and Professions Code. Reference: Sections 4040, 4057, 4081 and 4332, Business and Professions Code.

To Amend §1250.4 in Chapter 12 of Part 2 of Title 24 of the California Code of Regulations to read as follows:

1250.4 Sterile Compounding Area ~~for Parenteral Solutions~~.

The pharmacy shall have a designated area for the compounding of sterile preparations for dispensing which shall:

1. In accordance with ~~Federal Standard 209(b), Clean Room and Work Station Requirements, Controlled Environment as approved by the Commission, Federal Supply Service, General Services Administration meet standards for class 100~~ ISO 14644-1 Cleanrooms and associated controlled environments – Part 1 Classification of air cleanliness the environment inside the PECs must meet the standards for ISO Class 5 and buffer areas (cleanrooms) must meet ISO Class 7 through HEPA (high efficiency particulate air) filtered air ~~such as laminar airflow hood or clean room~~ resulting in less than 3520 and 352,000 respectively of particles less than 0.5 µm and larger per cubic meter measured under dynamic operating conditions.

2. Have nonporous and cleanable surfaces, ceilings and ceiling tiles, walls, floors and floor coverings.

3. The pharmacy shall be arranged in such a manner that the ~~laminar flow hood is~~ PECs are located in ~~an~~ area~~s~~ ~~which is~~ exposed to minimal traffic flow, and ~~is~~ separate from any area used for bulk storage of items not related to the compounding of ~~parenteral~~ solutions. There shall be sufficient space, well separated from the ~~laminar flow hood area~~ buffer area (cleanroom) for the storage of bulk materials, equipment and waste materials.

4. A sink with hot and cold running water must be ~~within the parenteral solution compounding area or adjacent to it~~ located adjacent to the sterile compounding area, however not inside the buffer area or immediately adjacent to the PEC located within the segregated compounding area.

5. Any pharmacy that compounds sterile ~~injectable~~ drug ~~products~~ preparations ~~from one or more nonsterile ingredients~~ must compound the medication in one of the following environments:

5.1 An ISO class 5 ~~laminar airflow hood~~ PEC(s) within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential of at least 0.02" water column positive relative to each adjacent areas.

5.2 ~~An ISO class 5 cleanroom.~~ The cleanroom must have a positive air pressure differential relative to adjacent areas.

~~5.3 A barrier isolator that provides an ISO class 5 environment for compounding.~~

5.3 A compounding isolator (either compounding aseptic isolator or compounding aseptic containment isolator) that provides an ISO Class 5 environment for compounding within an ISO Class 7 cleanroom unless documentation from the manufacturer of the barrier isolator permits operation of the barrier isolator in an environment that is cleaner than ISO Class 7.

6. When compounding hazardous drugs, the surrounding environment must provide at least 0.01 water column negative air pressure and 12 air changes per hour.

To Amend §505.5 in Chapter 5 of Part 4 of Title 24 of the California Code of Regulations to read as follows:

505.5 Pharmacies: Primary Engineering Controls for Non-Hazardous Sterile Compounding ~~Area of Parenteral Solutions~~. [CA – Board of Pharmacy] In all pharmacies preparing non-hazardous sterile drug preparations, all compounding shall be conducted within a certified laminar air flow workbench or compounding aseptic isolator. ~~The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall be ventilated in a manner not interfering with laminar air flow.~~

To Amend §505.5.1 in Chapter 5 of Part 4 of Title 24 of the California Code of Regulations to read as follows:

505.5.1 Pharmacies: ~~Laminar Flow Biological Safety Cabinet.~~ Primary Engineering Controls for Hazardous Drug Compounding. [CA – Board of Pharmacy]

In all pharmacies preparing ~~parenteral cytotoxic~~ hazardous agents, all compounding shall be conducted within a certified Class II Type A2 ~~or~~ Class II Type B2 or compounding aseptic containment isolator. ~~vertical laminar airflow hood with bag in-bag out design. The pharmacy must ensure that contaminated air plenums that are under positive air pressure are leak tight.~~

Attachment 2

Code Section	Commenter	Comment	Board Response
1735	Charles A. Reynolds, Pharm.D., B.C.P.P UCLA Health System	What is the basic purpose of this level of record keeping for a hospital pharmacy when one of the requirements is not the patient's name (e.g., not used for recalls)?	1735.3 are records that are required, and they are needed to ensure PHY/HSP have compounded in compliance with the regulations to ensure safe compounding for patient wellbeing
1735(a)	PharMEDium Services, LLC Rich Kruzynski	"Compounding" means any of the following activities occurring in a licensed pharmacy or outsourcing facility, by or under the supervision of a licensed pharmacist ~~pursuant to a prescription~~:	Reject - Outsourcing facilities will be subject to separate licensing requirement (503b).
1735(b)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	One of the major topics in the proposed regulation changes deals with new parameters for ophthalmic medications. Though some interpretations of the term "topical" may include ophthalmic solutions and suspensions, this sub-section's meaning would be more clear of the term "ophthalmic" was added after the term "topical".	disagree: does not apply to 1735(b) ophthalmic are sterile compounds and there are NONE that require only reconstitution per manufacture direction.
1735(c)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	This sub-section's meaning has been misunderstood and should be changed in this regulatory change process since the Board of Pharmacy is proposing a change in this sub-section. By defining in this sub-section what is NOT compounding in previous sub-section "(b)" and thus defining activities that are NOT subject the regulations and then doing the same for this sub-section "(c)" it has been interpreted that such activities are also not subject to the regulation. Conversely, it has been interpreted that the intent of this sub-section is just the opposite, i.e. that other than in "small quantities …" preparation of a product that is commercially available or is essentially a copy of a commercially available, though allowed for shortages per a subsequent regulation in the proposed changes, IS compounding and subject to these regulations. Also the change of the term "product" to "preparation" as proposed further confuses the sub-section as it is the intent of the Board to use the term "preparation" when something is pharmacy-compounded and the term "product" when the medication is commercially available.	agreed - removed sub-section (c) from language.
1735(c)	Central Admixture Pharmacy Services, Inc William Jones	"Product" should not be changed to "preparation" in this case. One would be making a copy of an approved drug product by compounding a sterile preparation.	removed sub-section (c) from language.
1735(c)	Douglas Barcon, Pharm.D., Barcon & Associates	Consider adding a limitation at the end of the last sentence by addressing paragraph (d)(3) in 1735.2. Compounding Limitations and Requirements; Self-Assessment.	removed sub-section (c) from language.
1735.1	California Pharmacist Association Brian Warren	We recommend the following modifications to Section 1735.1: "Daily" means occurring every day that a pharmacy is operating. "Primary Engineering Control (PEC)" means a device that provides an ISO Class 5 environment or better through the use of unidirectional HEPA filtered first air. Specific PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, compounding aseptic isolators, and compounding aseptic containment isolators. "Segregated sterile compounding area" means a designated space where a ~~device that provides unidirectional airflow of ISO Class 5 air quality, including compounding aseptic isolators~~, PEC is located within either a demarcated area (at least three foot perimeter) or room. Such area shall **not** contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated **sterile** compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation, and shall not have a sink located within at least three feet of the ~~ISO Class 5~~ PEC. ~~This~~ **The segregated** sterile compounding area ~~will~~ **shall** be restricted to preparing sterile-to-sterile compounded preparations.	Agreed - Changes incorporated.
1735.1	Douglas Barcon, Pharm.D., Barcon & Associates	Should there be an added definition to this regulation for a tacky mat or similar device to capture and minimize tracking of particles on the floor into the anteroom and ISO Class 7 buffer rooms, and should such a device be required or recommended, or should this be left to the PIC or the institutional or corporate policies and procedures and not codified in regulations?	Disagree: It is up to the facility to do determine how to keep the cleanroom particle free.
1735.1	PharMEDium Services, LLC Rich Kruzynski	Add: (2) "Outsourcing facility" means a facility at one geographic location or address that is engaged in anticipatory compounding of sterile drugs and complies with the United States Food and Drug Administration Section 503B of the Federal Food, Drug, and Cosmetic Act.	Reject - Outsourcing facilities will be subject to separate licensing requirement (503b).

Code Section	Commenter	Comment	Board Response
1735.1	Providence Heath & Services Southern California Region	Providence recommends adding definitions of the following primary engineering controls as per the USP 797 definitions to assist with understanding of the terminology for sterile compounding PECs. Biological Safety Cabinet(BSC): A ventilated cabinet for CSPs, personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward hiqh-efficiency air (HEPA)-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Compounding Aspetic Containment Isolator (CACI): A compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.	Agreed: Definitions added
1735.1	Providence Heath & Services Southern California Region	Compounding Aseptic Isolator (CAI): A form of isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum)	Agreed: Definition Added
1735.1(a)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommend removing "(also called ante room)" as this is different than what is currently required under regulation. There is a designated buffer area and ante area, and no enclosed "room" requirement.	Agreed: "(also called ante room)" removed.
1735.1(a)	BJ Bartleson, RN, MS, NEA-BC California Hospital Association	*1735.1 Compounding Definitions Where appropriate in the definitions section add the following terms:* 1.Add a definition of "adjacent" to allow for hospital construction. 2.Add a definition of "warehouse" to differentiate it from a pharmacy that may be built in a building constructed as a warehouse. 3. Add a definition for single dose container. 4.Add a definition for humidity 1735.1 (a) Ante-Area Recommend removing "(also called ante room)" as this is different than what is currently required under regulation. There is a designated buffer area and ante area, and no room requirement.	Disagree: Defining adjacent will not allow HSP to do construction any different than they are currently able to. Warehouse is defined in BPCs Single dose container is defined in 1751.9(a) Humidity removed from language.
1735.1(a)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommended ADDITIONAL Definitions 1. "Prescriber's office" includes traditional unlicensed prescribers offices and licensed health-care facilities where prescribers order, administer and dispense compounded preparations. Rationale: pharmacists compounding in all environments where compounded preparations are used improves the safety of health-care 2. "End-product examination": means a pharmacist will physically examine the final product to ensure that it meets specifications in the master formula. Using the term "end-product examination" and not the terms "end-product evaluation" or "end-product-testing", though possibly considered synonymous will avoid confusion. Using all three terms in the regulations is not only confusing to pharmacist but has been a continued source of confusion for Board Inspectors. Further Rationale: The master formula should contain the parameters for determining a consistent and successful compounding of the preparation regardless of who did the compounding. These parameters would include characteristics determined by the pharmacist in charge based on standards in the industry for compounding	1) Prescriber's office definition changed. No PHY should be compounding and selling to a PHY for dispensing this is manufacturing not compounding. 2) Disagree - There is no way a RPH can visible say the concentration, sterility or level of pyrogens meet the specification in the master formula.

Code Section	Commenter	Comment	Board Response
1735.1(a)	California Society of Health-System Pharmacists Dawn Benton	Recommend additional definition of “prescriber’s office” to include traditional unlicensed prescribers offices and licensed health-care facilities where prescribers order, administer and dispense compounded preparations. Rationale: pharmacists compounding in all environments where compounded preparations are used improves the safety of health-care. Recommend additional definition “end-product examination”: a pharmacist will physically examine the final product to ensure that it meets specifications in the master formula. Recommend only using the term “end-product examination” and not the terms “end-product evaluation” or “end-product testing” though we consider these to be synonymous. Using all three terms in the regulations is confusing. Rationale: The master formula should contain the parameters for a successful compounding of the preparation. These parameters would include characteristics determined by the pharmacist in charge based on standards in the industry for compounding. Recommend removing “(also called ante room)” as this is different than what is currently required under regulation. There is a designated buffer area and ante area, and no room requirement.	Prescriber's office definition changed. No PHY should be compounding and selling to a PHY for dispensing this is manufacturing not compounding. Disagree - There is no way a RPH can visible say the concentration, sterility or level of pyrogens meet the specification in the master formula. Agreed: “(also called ante room)” removed from language.
1735.1(a)	Sutter Health Jeannette Hanni	Recommend removal of the parenthesis comment (also called ante-room). It is not a room but a "space".	Agreed: “(also called ante room)” removed from language.
1735.1(b)	Cedars-Sinai Katherine Palmer Rita Shane	USP 797 defines batches as >25 compounded medications in the context of high risk (non-sterile to sterile) preparations or extended dating. Recommend using the same quantity to define sterile to sterile batches.	Disagree- changing this will mean that a PHY can high-risk compound but not test their products before dispensing as long as there are <24 items.
1735.1(b)	Sutter Health Jeannette Hanni	Remove "batch" definition as stated. Language already exists associated with low and medium risk compounded sterile preparations (CSPs). The term "batch" should only apply to high-risk CSPs, where end product testing representative samples is specifically required in CA1751.7e and USP797. Recommend redefining "batch" only in the context of high-risk preparations as describe in USP797	Agreed: "Batch" removed from language

Code Section	Commenter	Comment	Board Response
1735.1(b)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommend defining “batch” as a quantity sufficient for sterility testing in high risk compounding preparations e.g. sterile from non-sterile ingredients, and prepared in quantities sufficient for testing sterility and within a period with sufficient time to receive results before required administration and in a quantity that can be tested without destroying all the finished preparation. Rationale: There is no benefit in defining a batch for sterile to sterile transfers, whether for a single dose or multiple doses. There is already language in existing and proposed regulations that limit the risk associated with low and medium risk compounded sterile preparations (CSPs). For example: media fill tests are already required for personnel compounding these types of preparations (1751.7(b)). The term “batch” should only be applicable for high-risk CSPs, where end-product testing of representative samples is specifically required in California Regulations (1751.7(e)) and USP Chapter 797. Rationale: The definition of “batch” must be inserted into the regulatory requirements anywhere the term is used in order to determine its impact. The use of this definition creates problems in other parts of the proposed regulations. For example, 1751.4(d)(2) states that cleaning and disinfecting surfaces in the ISO Class 5 hood shall occur before and after each batch. If a batch is defined as two or more doses as described in 1735.1(b), pharmacy personnel would be required to perform hood cleaning up to several hundred times per day. The “Batch” definition from USP Chapter 797 applies only to “All high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampules, bags, syringes, vials) or in multiple-dose vials (MDVs) for administration to multiple patients or that are exposed longer than 12 hours at 2 degrees C to 8 degrees C and longer than 6 hours at warmer than 8 degrees C before they are sterilized shall meet the sterility test (see Sterility Tests <71>) before they are dispensed or administered.”	Agreed: "Batch" removed from language
1735.1(b)	California Society of Health-System Pharmacists Dawn Benton	Recommend defining “batch” as a quantity sufficient for sterility testing in high risk compounding preparations e.g. sterile from non-sterile ingredients, and quantities sufficient for testing sterility in the time period before required administration. Rationale: The definition of “batch” must be inserted into the regulatory requirements anywhere the term is used. As used in the proposed regulation the term would not be consistent with industry standards. e.g. USP 797 or the practice of pharmacy and would have substantial adverse impact on hospital efficiency, cost and timely therapy and thus also adversely affect patient safety and access to necessary medication therapy..	Agreed: "Batch" removed from language
1735.1(b)	BJ Bartleson, RN, MS, NEA-BC California Hospital Association	Recommend modifying definition to: “batch means compounding, at any risk level, of two or more finished drug preparation units produced during the same continuous cycle of compounding and prepared in advance for patients yet to be identified	Agreed: "Batch" removed from language
1735.1(b)	California Council for the Advancement of Pharmacy: Paige Talley, Management Consultant	Currently, USP <797> defines a batch as more than 25; and CCAP recommends that the board follows the USP <797> guidelines.	Agreed: "Batch" removed from language
1735.1(b)	Charles A. Reynolds, Pharm.D., B.C.P.P UCLA Health System	USP 797 does not define a batch as two or more finished drug preparations. A batch size of more than 25 identical containers is the cutoff for additional testing (e.g. sterility and endotoxin) according the USP 797. This definition should be used instead in the regulations for consistency with USP 797.	Agreed: "Batch" removed from language

Code Section	Commenter	Comment	Board Response
1735.1(b)	Douglas Barcon, Pharm.D., Barcon & Associates	The definition of batch has been a point of contention for quite some time, and there are valid arguments with every definition. It is difficult to consider a batch to be two finished drug preparation units when a person is compounding two Zosyn 13.5 gram multi-dose infusions or continuous infusions for the same patient. Perhaps a batch should be more than two finished drug preparations units for one or more patients, as well as any multiple dose vials prepared for administration to more than one patient.	Agreed: "Batch" removed from language
1735.1(b)	Harbor Compounding Pharmacy Mai Tran and Sam Kitahara	We recommend the definition of "batch" to be changed to: "Batch" means compounding of a preparation that is used for more than one patient (regardless of the number of finished drug preparation units) produced during the same continuous cycle of compounding.	Agreed: "Batch" removed from language
1735.1(b)	Providence Heath & Services Southern California Region	"Batch" means compounding of finished drug products in groups of more than 25 units (optional:"or single-dose packages") produced during the same continuous cycle of compounding and shall include any multiple dos vials prepared for administration to more than one patient. The testing requirements under USP 797 for high-risk level CSPs apply only to batches of more than 25 units.	Agreed: "Batch" removed from language
1735.1(c)	Harbor Compounding Pharmacy Mai Tran and Sam Kitahara	We recommend the definition of "beyond use date" to be changed to: "Beyond use date" means the date or date and time after which a compounded drug preparation shall not be dispensed or administered.	Agreed: "Beyong use date" definition changed.
1735.1(d)	Charles A. Reynolds, Pharm.D., B.C.P.P UCLA Health System	This definition of a buffer area, along with the definition for segregated compounding area and designated compounding area only relates to the USP 797 cleanroom setting. In the non-USP 797 cleanroom setting, additional definitions are needed to define the compounding area, which is the ISO Class 5 laminar airflow hood. Without these additional definitions, there will be confusion in most hospital settings where 'Satellite Pharmacies' have an ISO 5 laminar airflow hood in a non-ISO room for 'first doses' to be administered immediately.	Reject: Refer to section 1751.8(f)
1735.1(e)	Harbor Compounding Pharmacy Mai Tran and Sam Kitahara	This is a confusing definition. Does this bulk drug definition apply to inactive ingredients such as bulk base creams and capsule fillers? This bulk drug definition is incorrect in that the bulk drug substance does NOT become an active ingredient in the dosage form of the drug. If so, we suggest changing the definition according to USP 795 guidelines: **Bulk Drug Substances**—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.	Reject: Definition applys to "Active" ingredients.
1735.1(f)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommend using the following definition for "cleanroom." "Cleanroom means a separate room or area with or without walls and doors that provides at least an ISO Class 7 or better area where the primary engineering control is located. The cleanroom may maintain segregation from the adjacent ante-area by means of specific pressure differentials. For cleanrooms providing a physical separation through the use of walls, doors, and pass-through, a minimum differential positive pressure of 0.02- to 0.05-inch water column is required. For buffer areas not physically separated from the ante-areas, the principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. Using displacement airflow typically requires an air velocity of 40 ft per minute or more from the buffer area across the line of demarcation into the ante-area. The displacement concept shall not be used for high-risk compounding. Rationale: The industry standard, USP 797, does not describe the cleanroom as a physically separate room with walls and doors but can be separated through appropriate differentials in air flow from the "ante-areas."	Agreed: Definition updated in language

Code Section	Commenter	Comment	Board Response
1735.1(f)	California Pharmacist Association Brian Warren	~~(f) "C leanroom"(which may also be referred to as a buffer area) means a physically separate room with walls and doors providing at least an ISO Class 7 or better air quality where the primary engineering control is physically located. This room maintains segregation from the adjacent ante-area (ante-room) by means of specific pressure differentials. For rooms providing a physical separation through the use of walls, doors, and pass-throughs, a minimum differential positive pressure of 0.02- to 0.05-inch water column is required. For buffer areas not physically separated from the ante-areas, the principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. Using displacement airflow typically requires an air velocity of 40 ft per minute or more from the buffer area across the line of demarcation into the ante-area. The displacement concept shall not be used for high-risk compounding.~~ We recommend the following modification: (f) (1) "Compounding aseptic isolator " means a form of isolator specificall y designed for compounding drug preparations designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer process, with no air exchange into the isolator from the surrounding environment unless the air has first passed through a microbial retentive filter. (2) "Compounding aeptic containment isolator " means a form of compounding aseptic isolator designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer process and to provide an aseptic environment for compounding sterile drug preparations, with no air exchange into or out of the isolator unless the air has first passed through a microbial retentive filter system capable of containing airborne concentrations of the physical size and state of the drug being compounded, and where the exhaust air from the isolator is appropriately removed by properly designed building ventilation when volatile hazardous drugs are compounded	Reject: Cleanroom definition retained. Other definitions added
1735.1(f)	Douglas Barcon, Pharm.D., Barcon & Associates	Consider pressure differentials for hazardous drug compounding in a negative pressure room within a cleanroom suite, which should be at least 0.01 inches negative pressure of water column relative to other surrounding controlled pressure rooms (per USP 800), including ISO Class 7 buffer rooms and ante rooms. Current proposed text states: Using displacement airflow typically requires an air velocity of 40 ft per minute or more from the buffer area across the line of demarcation into the ante-area. The displacement concept shall not be used for high-risk compounding. The proposed text does not state, as per USP 797 under Hazardous Drugs as CSPs, that hazardous drugs shall be prepared in a room that is physically separated from other preparation areas, and that the concept of airflow displacement shall not be used for hazardous drug compounding. Airflow displacement is not a physical separation. USP 800 also requires a separate area. Suggest changing the last sentence in the proposed text to read: "The displacement concept shall not be used for high-risk compounding or for hazardous drug compounding."	Reject: However, definition was updated in language.
1735.1(f)	California Society of Health-System Pharmacists Dawn Benton	Recommend using the following definition for "cleanroom." "Cleanroom means a separate room or area with or without walls and doors that provides at least an ISO Class 7 or better area where the primary engineering control is located. The cleanroom may maintain segregation from the adjacent ante-area by means of specific pressure differentials. For cleanrooms providing a physical separation through the use of walls, doors, and pass-through, a minimum differential positive pressure of 0.02- to 0.05-inch water column is required. For buffer areas not physically separated from the ante-areas, the principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. Using displacement airflow typically requires an air velocity of 40 ft per minute or more from the buffer area across the line of demarcation into the ante-area. The displacement concept shall not be used for high-risk compounding. Rationale: USP 797 does not describe the cleanroom as a physically separate room with walls and doors but can be separated through appropriate differentials in airflow from the "ante-areas."	Agreed: Definition updated in language

Code Section	Commenter	Comment	Board Response
1735.1(f)	McGuff Compounding Pharmacy Services, Inc William J. Blair, Pharm.D., MBA Vice President and Director of Pharmacy Services	Comment: do not use a range to define a minimum number	Reject: Range needed
1735.1(o)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommend using the standard dictionary term of "parenteral" which means "other than by the enteral route". It does not include only injections through the skin. Rationale: The new proposed definition is inconsistent with common usage and usage within the medical and pharmacy professions.	Agreed: Definition changed in language
1735.1(g)	California Society of Health-System Pharmacists Dawn Benton	Recommend referencing USP N.F. 37-NF-32 for Section 1735.1 (g) though (i). Rationale: proposed regulation does not match industry standards as they evolve and is too specific for practical application	Agreed: Temperature requirements changed in language
1735.1(g)	BJ Bartleson, RN, MS, NEA-BC California Hospital Association	Recommend use of current USP temperatures Of 2-8 degrees C. referencing USPN.F 37-NF-32	Agreed: Temperature requirements changed in language
1735.1(g)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	There is conflict between how the BOP is proposing to define "controlled cold temperature" and how USP and CDC are defining it (2 degrees to 8 degrees C). Consider alignment of the proposed BOP definition with that of USP and CDC. As an alternative, consider including verbiage "The preparation may be stored at an alternate temperature range in accordance with the manufacturer's recommendations or literature". Concern the CSBOP may consider a facility noncompliant if a medication was stored at for example 2 degrees F despite the fact that the facility is storing the medication in accordance with the manufacturer's recommendations or information in the literature.	Agreed: Temperature requirements changed in language
1735.1(g)	McGuff Compounding Pharmacy Services, Inc William J. Blair, Pharm.D., MBA Vice President and Director of Pharmacy Services	Comment: Should use USP definition of "Controlled cold temperature" of 2 degrees to 8 degrees. No need for tenths which cannot be accurately measured on many thermometers.	Agreed: Temperature requirements changed in language
1735.1(h)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	To determine if the proposed definition encompasses a range of compounded sterile products that require "freezer" temperatures would require a comprehensive review of the literature. Concerned that the proposed definition does not encompass the temperatures of commercially available medications stored in the freezer in accordance with the manufacturer recommendations that may be comingled with the compounded preparations. For example, cervidil vaginal inserts should be stored in the freezer between –20 degrees C and – 10 degrees C, Baxter frozen premixed products must be stored at or below – 20 degrees C, Varivax© should be stored between –50 degrees C and –15 degrees C. Concern is that following the proposed "controlled freezer temperature" could lead to facilities storing medications in a freezer at a temperature that is not consistent with the manufacturer's recommendations or what is recommended in the literature in the case of a compounded medication. Consider adding the sentence "Medication preparations may be stored at an alternate temperature range in accordance with the manufacturer's recommendations or literature".	Agreed: Temperature requirements changed in language. Language updated to include manufacturer's recommendations.
1735.1(i)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	The proposed definition encompasses the usual and customary working environment of 20 degrees to 25 degrees C (68 degrees to 77 degrees F) but USP General Notice 10.30.40 allows for transient excursions between 15 degrees C and 30 degrees C (59 degrees to 86 degrees F). Consider aligning with the USP General Notice.	Disagreed. PHY needs to have a controlled temp not just in the compounding area but anywhere the drugs are stored. Adding in the ability for excursions could result in a PHY NOT turning on the AC when the PHY is closed on summer weekends.

Code Section	Commenter	Comment	Board Response
1735.1(k)	Community Regional Medical Center Bruce Lepley, Director of Pharmacy	Reason for Concern: The definition is not used in the body of the proposed regulations. If the definition is not used this may lead to confusion by leaving it in the definition section. Solution: Remove section that defines “first air” altogether	Disagree: See (ab) PEC definition
1735.1(o)	California Society of Health-System Pharmacists Dawn Benton	Recommend using the dictionary definition of parenteral that means “other than by the enteral route”. Rationale: the proposed definition is inconsistent with statutory language and common usage.	Agreed: Definition changed in language
1735.1(o)	Providence Heath & Services Southern California Region	"Parenteral means a ~~sterile~~ preparation of drugs ~~for injection or implantation through one or more layers of skin~~ to be administered in a manner other than through the digestive tract. This includes, but is not limited to, injection through one or more layers of skin, administration into the eye and by inhalation. Providence recommends that the regulatory definition should be consistent with medical definition of "parenteral" and SB 294 [Article 7.5, Sec 3. 4127(a)].	Agreed: Definition changed in language
1735.1(q)	BJ Bartleson, RN, MS, NEA-BC California Hospital Association	Recommend eliminating potency testing requirements for the following three scenarios: 1. A compounded drug product where the full prepared quantity will be delivered in the original diluent contained in Manufacturer produced overfill 2. Manufacturer written communication (PI, Letter, email) stating that a particular prep has been tested 3. Scientific article from refereed journal identifying stability	Reject: Recommendation not responsive to definition. Not addressed in regulation.
1735.1(q)	Sutter Health Jeannette Hanni	Recommend adding an exemption fpr any compounded drug product where the full, prepared quantity will be delivered and the original diluent contained a manufacturer produced "overfill".	Reject: Recommendation not responsive to definition. Not addressed in regulation.
1735.1(q)	Charles A. Reynolds, Pharm.D., B.C.P.P UCLA Health System	An ISO class 5 laminar airflow hood in and of itself should meet the requirements of this definition. The addition of a 3 foot demarcated area surrounding the ISO5 laminar airflow hood may eliminate the possibility of compounding in an existing satellite pharmacy. USP 797 does not include the 3 foot perimeter demarcation in the definition of a segregated compounding area and it should be removed from the Board’s definition. Keeping this definition may exclude compounding areas already built and in use for sterile compounding. If the ISO Class 5 laminar airflow hood meets this definition of a ‘segregated compounding area’, the remainder of the regulation must be edited to account for this fact. The compounding area of this kind of laminar airflow hood is a ‘designated space that is restricted to preparing sterile-to-sterile compounding’. If this regulation is not edited to include the practices occurring in a Pharmacy Satellite (non-USP 797 cleanroom area) compounding of sterile products will once again revert to being done by nursing staff in the medication room, as it is not possible with a centrally located IV room to respond to the immediate needs of ICU patients for compounded drips and first dose sterile products for all other patients. Under the pressure of timeliness, the preparation of sterile products will once again become the purview of the nursing staff. <u>This is not to be viewed as a step forward for medication safety. It will increase wastage and will result in movement of preparations to the bedside by nursing which is a less safe practice than current pharmacy standard clinical practice around sterile compounding</u>.	Reject: Refer to section 1751.8(f)
1735.1(t)	Douglas Barcon, Pharm.D., Barcon & Associates	Add at end “for the exposure of critical sites when compounding sterile preparations,” in order to bring closer to the definition of PEC in USP 797 while also matching board of pharmacy terminology.	Agreed: Definition changed in language
1735.1(t)	Harbor Compounding Pharmacy Mai Tran and Sam Kitahara	We want to make sure that the definition of a PEC means specifically for devices that are used in the compounding of compounded sterile preparations. We suggest changing to “Primary Engineering Control” means a device that provides an ISO Class 5 environment or better through the use of unidirectional HEPA filtered first air <u>when compounding compounded sterile preparations.</u>	Agreed: Definition changed in language

Code Section	Commenter	Comment	Board Response
1735.1(w)	Harbor Compounding Pharmacy Mai Tran and Sam Kitahara	Current labeling guidelines for non-sterile compounded preparations do not require the labeling of inactive ingredients on the label (only the active pharmaceutical ingredient). If so, then the definition of quality is not applicable since if the compounded non-sterile preparation contains inactive ingredient "glycerin," and if the label says it is Progesterone 200mg/ml cream, then according to the proposed definition of quality, because the label only lists progesterone and does not list glycerin, then this is of subpar quality because the progesterone cream contains glycerin when it's not supposed to. We suggest changing the definition to eliminate the word inactive ingredients: "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.	Agreed: Definition changed in language
1735.1(x)	GrayMatter Pharmacy Services, Inc Michael Moore, R.Ph.	What is a three foot perimeter? Do you mean that the demarcated area needs to extend three feet in all directions from the isolator? Three feet from the opening? I believe I have spoken before about the problems small hospitals have with compliance on this issue. Requiring additional space will make compliance more difficult for small pharmacies. "…Such area shall contain and shall be void of activities and materials…" I cannot understand this phrase. It is a contradiction to both "contain" and "be void of".	Reject: 3 foot perimeter is for patient safety and mandatory.
1735.1(x)	Sutter Health Jeannette Hanni	Recommend adding a definition of "adjacent" in order to allow for hospital construction. Recommend adding a definition of "warehouse" in order to differentiate it from a pharmacy that may be built in a building constructed as a warehouse.	Disagree: Defining adjacent will not allow HSP to do construction any different than they are currently able to. Warehouse is defined in BPCs
1735.1(x)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommendation: Use the definition of Segregated Compounding Area in USP Chapter 797: A designated space, either a demarcated area or room, that is restricted to preparing low-risk level CSPs with 12-hour or less BUD. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of CSPs and shall be void of activities and materials that are extraneous to sterile compounding.	Reject: Must include 3 foot perimeter and cannot use "Low-risk" language.
1735.1(x)	Douglas Barcon, Pharm.D., Barcon & Associates	**Such area shall contain and shall be void of activities and materials that are extraneous to sterile compounding.** Confusing sentence in bold. Consider deleting "shall contain and." Alternatively, could add "not" between "shall" and "contain." Does adjacent include a warehouse in the unit next to a home infusion pharmacy that has a cleanroom and a segregated compounding area, where the businesses share a common wall between units? If there was no warehouse in the next unit when the cleanroom or segregated compounding area was installed but a warehouse was installed later by the new lessee, the pharmacy should not be expected to move the cleanroom or segregated compounding area. Perhaps a segregated compounding area should be specifically limited to hospitals and perhaps also skilled nursing facilities.	Agreed: Definition updated in language
1735.1(y)	Sutter Health Jeannette Hanni	Recommend removal of the smoke test definition as it is not used or referenced throughout the regulation.	Agreed: Definition Removed
1735.1(y)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommend removal of the "smoke test" definition. Rationale: Vague and confusing as proposed – The term is not used or referenced throughout the regulation; not industry standard. Further, the use of a "smoke test" in a hospital environment on patient floors in the drug rooms (aka "satellites" that the Board of Pharmacy requires to have a separate Sterile Compounding License has not been evaluated for patient safety and impact on the patient care environment.	Agreed: Definition Removed
1735.1(y)	California Society of Health-System Pharmacists Dawn Benton	Recommend removal of the smoke test definition. Rationale: Vague and confusing as proposed - not used or referenced throughout the regulation; not industry standard.	Agreed: Definition Removed

Code Section	Commenter	Comment	Board Response
1735.1(y)	BJ Bartleson, RN, MS, NEA-BC California Hospital Association	Recommend removal of the smoke test definition as it is not used or referenced throughout the regulation.	Agreed: Definition Removed
1735.1(y)	Providence Heath & Services Southern California Region	~~"Smoke test" means an analysis of the airflow in the ISO Class 5 PEC using a smoke generating device.~~ **Providence recommends removal of the smoke test definition as it is not used or referenced throughout the regulation.**	Agreed: Definition Removed
1735.2	Unknown Speaker at Hearing	Conflicts with 1751.8 beyond use dates. Clarification required on whether judgment of pharmacist supersedes 1751.8 limits	Disagree: 1735.2(I) is talking about the assignment of the BUD not how to use the BUD after assigned as in 1735.1
1735.2	San Mateo Medical Center Gary L. Horne, Director of Pharmacy	Consider adding language such as *"Exempt from the requirements in this paragraph are sterile preparations compounded on* ***a one-time basis for administration*** *within seventy-two {72} hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia- National Formulary {USP37-NF32} Through 2nd Supplement {37th Revision, Effective December 1, 2014), hereby incorporated by reference.*	Disagree: the only exemption is from 1735.3 for the Manuf, Exp date and lot number of each Component.
1735.2(a)	Central Admixture Pharmacy Services, Inc William Jones	Change the wording in (a) to read: Except as specified in (b), (c), or (d) no drug product preparation shall be compounded …. Insert a new section (d) to read: "The pharmacy is a 503B FDA registered Outsourcing Facility."	Reject - Outsourcing facilities will be subject to separate licensing requirement (503b).
1735.2(b)	The Institute for Community Pharmacy John Cronin	**(1)** A pharmacy may prepare and store a limited quantity of a compounded drug product preparation in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population. **Add: (2) A pharmacy may compound preparations without the valid prescription for an individual patient required by subsection (a) for the purposes of clinical research that complies with requirements of the federal Food and Drug Administration (FDA).** ICP encourages the Board to deal with the issue of compounding for the purpose of clinical research. We believe the suggested language addresses this issue. However, our primary objective in making this suggestion is to have the Board resolve an issue that is not currently addressed in California law.	Reject: Not for patient use.
1735.2(c)(1)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Omit in sub-section 1735.2(c)(1) the requirement that the order "that lists the number of patients 'seen' or 'to be seen' and the "quantity for each patient" and replace it with a requirement for an "estimate" of that information, instead of placing the phrase "as estimated by the prescriber" at the end of the sub-section. Rationale: Saying first that the order must "list the number" and "quantity for each patient" and then saying it may be estimated adds to the confusion of what is required.	Disagree: a prescriber needs to be able to estimate how many patients a drugs supply should be used on.
1735.2(c)(1)	McGuff Compounding Pharmacy Services, Inc William J. Blair, Pharm.D., MBA Vice President and Director of Pharmacy Services	Comment: Listing the number of patients would require a prescriber to utilize his/her best guess. We do not see any added value to the prescriber, patient or pharmacy as the prescribers order is already his best guess for the future. We would anticipate the "number of patients to seen or to be seen" would always match the doses ordered.	Disagree: a prescriber needs to be able to estimate how many patients a drugs supply should be used on.
1735.2(c)(1)	Harbor Compounding Pharmacy Mai Tran and Sam Kitahara	Is order by the prescriber or his/her representative, and paid for by the prescriber	Agreed: Language updated

Code Section	Commenter	Comment	Board Response
1735.2(c)(1)	California Council for the Advancement of Pharmacy: Paige Talley, Management Consultant	The requirement of the pharmacy to be furnished a list of the number of patients to be seen is unreasonable when the number of patients may be inferred by the number of doses provided to the physician for a 72-hour period. CCAP recommends that the Board of Pharmacy removes that requirement from the proposed regulations.	Disagree: a prescriber needs to be able to estimate how many patients a drugs supply should be used on.
1735.2(c)(2)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommendation: Replace sub-section 1735.2(c)(2) with "is delivered to the prescriber's office and signed for by the prescriber or prescriber's agent," Rationale: The prescriber signature requirement is impractical and overly burdensome. In an office practice, the prescriber is not always immediately available. It is common for nurses and medical assistants to receive supplies and medications on behalf of physicians and other prescribers.	Agreed: Language updated
1735.2(c)(2)	California Society of Health-System Pharmacists Dawn Benton	Recommend deleting "is delivered to the prescriber office" and adding "or their agent". Rationale: the requirement for a physician or other prescriber to personally sign for the receipt of compounded products is beyond the scope of authority of the Board of Pharmacy and the ability of pharmacists to enforce thus potentially denying patients access to the safety of pharmacist compounded preparations. The ability of physicians and other prescribers to function through authorized agents is clearly established under California law.	Agreed: Language updated
1735.2(c)(2)	California Pharmacist Association Brian Warren	We recommend the following modification to Section 1735.2 (c)(2): (2) is delivered to the prescriber office and signed for by the prescriber or the prescriber's agent.	Agreed: Language updated
1735.2(c)(2)	Harbor Compounding Pharmacy Mai Tran and Sam Kitahara	Is delivered to the prescriber office and signed for by the prescriber or his/her representative	Agreed: Language updated
1735.2(c)(2)	McGuff Compounding Pharmacy Services, Inc William J. Blair, Pharm.D., MBA Vice President and Director of Pharmacy Services	Comment: This assumes a prescriber is always available in an "office" when a delivery takes place. Delivery of compounded drugs from different sources, different delivery companies, at random delivery times would unnecessarily restrict prescriber to his/her office, take the prescriber away from professional duties to see patients. A compounded drug is a prescription drug the same as a commercially available drug. Commercially available drugs do not have this signature requirement. Why create a difference? Receipt of drugs and devices can and should be delegated.	Language updated
1735.2(c)(2)	California Council for the Advancement of Pharmacy: Paige Talley, Management Consultant	Given that the prescriber is not always in his/her office, it would be more efficient to require that the prescriber or the prescriber's agent or authorized licensed staff sign for the delivery of compounded medications.	Agreed: Language updated
1735.2(d)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommendation: Define this term in 1735.1, as an exact copy of a commercially-available drug (exact same chemical entity, dose, volume, diluent) so that interpretation issues do not arise regarding the definition. Rationale: The meaning of this language is unclear. Does "copy" mean the exact drug product? A generic version of a branded drug? A therapeutic substitution of a drug?	Agreed: Definition Added to language
1735.2(d)(3)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommendation: Replace "ASHP" with "industry standard drug shortage list." Also, we recommend adding language to address drugs not yet placed on a national or State shortage list but actually in short supply at the patient care level. Rationale: exclusive reliance on ASHP or the FDA shortage lists does not recognize the common existence of local product shortages and the delay in inclusion of shortage products on those lists.	Disagree: We need to have a standard list to hold compounders to and the lists are update quickly, so no need to have a loop hole! And LOCAL shortage means the drug is still available in US and needs to be shipped!

Code Section	Commenter	Comment	Board Response
1735.2(d)(3)	California Society of Health-System Pharmacists Dawn Benton	Recommend replacing "ASHP" with "industry standard drug shortage list." Recommend adding language to address drugs not yet placed on a shortage list. Rationale: exclusive reliance on ASHP or the FDA shortage lists does not recognize the common existence of local product shortages and the delay in inclusion of shortage products on those lists.	Disagree: We need to have a standard list to hold compounders to and the lists are update quickly, so no need to have a loop hole! And LOCAL shortage means the drug is still available in US and needs to be shipped!
1735.2(d)(3)	McGuff Compounding Pharmacy Services, Inc William J. Blair, Pharm.D., MBA Vice President and Director of Pharmacy Services	Comment: Currently, the FDA does not monitor end users or wholesalers for drug shortages. FDA relies upon manufacture's statements that a drug is no longer on shortage. Patients need these drugs compounded when they are not available. In addition, remove "at the time of dispense" as any drug compounded, in limited quantities, in good faith during the shortage should be allowed to be dispensed.	Disagree: If the phy wants to compound it as a drug in shortage they will need to have the documentation as such.
1735.2(d)(3)	California Council for the Advancement of Pharmacy: Paige Talley, Management Consultant	There is concern that if a manufacturer has not conveyed to the FDA that there is a drug shortage, the drug in question will not be on the FDA list of drugs in short supply. Please include manufacturer availability.	Disagree - ASHP list can also be used
1735.2(d)(3)	Gary Horne: Hearing Testimony San Mateo Medical Center	Cannot compound sterile product that is commerically available. Exempt products for one time use for administration within 72 hrs for inpatient.	Reject: Conflicts with FDA
1735.2(d)(3)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	Many drug shortages that impact facilities do not appear on the "ASHP or FDA list of drugs that are in short supply". The medication in "short supply" may be a temporary supply interruption that impacts a region or a single facility in which case it may not appear or there may be a considerable delay in appearing on the ASHP or FDA list of drugs that are in short supply. Consider softening the language so as not to insert an unnecessary and potentially unsafe barrier to patients receiving a critically needed medication. In addition, consider deleting the verbiage "at the time of dispense". If a medication has been compounded after determining the preparation meets the requirements of this section, allow it's dispensing up until the beyond use date. It would be a waste of precious drug resources to not permit use of a compounded preparation that is still suitable for use but is no longer on the ASHP or FDA list.	Reject: Maintaining ASHP and FDA requirements. Need documents to show shortage
1735.2(e)	Gary Horne: Hearing Testimony San Mateo Medical Center	Record keeping burden to list master formula for products that are purchased	Reject: We are not asking for the master formula for non-compounded items.
1735.2(e)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommendation: Add a requirement for the Master Formula to contain as section on "End-Product Examination Criteria" Rationale: Regulation Section 1735, et seq. apply to all types of Pharmacy Compounding, non-sterile and sterile. Each type of preparation has criteria that should be used for the compounding pharmacist to determine the end-products appropriateness and consistency with previous preparations compounded using the same Master Formula.	Reject: That is what the post-compounding process is for. Can be part of pharmacy policy.
1735.2(e)	Harbor Compounding Pharmacy Mai Tran and Sam Kitahara	A drug preparation shall not be compounded until the pharmacy has first prepared a written or electronic master formula record that includes at least the following elements	Reject: Written does not mean hard copy

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1735.2(g)	Community Regional Medical Center Bruce Lepley, Director of Pharmacy	Reason for Concern: For hospital pharmacies using only sterile FDA approved products for compounded sterile products we are ensuring that the product contains the appropriate amount of active ingredient. In addition, we are not successful in finding any laboratories in our area that can assay products to determine the amount (e.g. milligrams) of active ingredient in a compounded sterile product. Many laboratories use liquid chromatography-mass spectrometry (LCMS) that uses mass analysis and physical separation techniques to determine if a substance displays the same LCMS properties as a reference compound. This assay does not determine for instance a milligram amount of a substance in a compounded product so it would not meet the proposed regulation. Solution: Remove "potency" from the "integrity" definition and remove the requirement of the pharmacy determining, maintaining, validating and monitoring potency for compounded products if the source of the CSP's come from sterile FDA approved products.	Reject: Not required
1735.2(f)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Rewording the regulation to use the word "frequency" instead of "routinely". as follows: "Where a pharmacy does not frequently compound a particular drug product preparation, the master formula record for that product preparation may be recorded on the prescription document itself or as appropriate for hospital practice, or in an electronic database.". Rationale: to clarify the application of this provision in hospitals and for preparations for administration in clinics and medical offices where prescription documents are not used for hospitalized and clinic or medical office patients. Changing "routinely" to "frequently" clarifies the intent is to promote consistency.	Disagree: Frequency and routinely are both subjective and there are orders in a HSP setting to record the information. The vagueness of "as appropriate for HSP" is not appropriate at all.
1735.2(f)	California Society of Health-System Pharmacists Dawn Benton	Recommend rewording this provision as follows: Where a pharmacy does not frequently compound a particular drug product preparation, the master formula record for that product preparation may be recorded on the prescription document itself or as appropriate for hospital practice, or in an electronic database. Rationale: to clarify the application of this provision in hospitals and for preparations for administration in clinics and medical offices where prescription documents are not used for hospitalized and clinic or medical office patients. Changing routinely to frequently to clarify the frequency.	Disagree: Frequency and routinely are both subjective and there are orders in a HSP setting to record the information. The vagueness of "as appropriate for HSP" is not appropriate at all.
1735.2(i)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Concern: The proposed wording "it should not be used" is ambiguous and not in concordance with USP Chapter 797 If this definition remains as written, it could be interpreted that the administration of a preparation should be stopped prior to completion, if the BUD is reached. This is not the intent of the BUD, and may lead to excessive changes/manipulations of preparations and an increased risk of harm. For example, a pharmacy could prepare 5-Fluorocuracil (5-FU), a cancer chemotherapy drug, for intravenous administration to a patient using a portable infusion pump in the home setting. 5-FU has a 30-hour beyond use date, and is infused over a period of 46 hours from a single drug container. If the proposed language is not changed, the beyond use date would be reached in the midst of the infusion; requiring that the infusion be stopped and the existing 5-FU drug container replaced with a new one. This would create the risk of error and possible infection. Recommendation: Change to the language proposed in 1735.1(c): "Beyond use date" means the date or date and time after which a compounded drug preparation shall not be stored or transported, or administration begun.	Reject: The definition 1735(b) already states the recommendation listed.
1735.2(i)	Harbor Compounding Pharmacy Mai Tran and Sam Kitahara	Every compounded drug preparation shall be given a beyond-use date representing the date beyond which, in the professional judgment of the pharmacy performing or supervising the compounding, it should not BE DISPENSED OR ADMINISTERED.	Reject: The definition 1735(b) already states the recommendation listed.

Code Section	Commenter	Comment	Board Response
1735.3	Charles A. Reynolds, Pharm.D., B.C.P.P UCLA Health System	While this may be applicable for compounding within a USP 797 compliant cleanroom, it is impossible and unnecessary to comply with this in a Pharmacy Satellite environment (non USP 797 compliant cleanroom) for first dose sterile to sterile compounding. The regulation as well as others within this proposal needs to be adjusted to allow for two kinds of hospital based compounding (satellite and central USP 797 cleanroom compounding). Otherwise this too will force intravenous medication preparation from the pharmacy to nursing at the bedside. What is the definition of a one-time basis? Clarification is needed so there is no ambiguity.	Reject: Refer to section 1751.8(f)
1735.3	San Mateo Medical Center Gary L. Horne, Director of Pharmacy	The following statement should apply to all paragraphs/sections of (a) {1) through (10)."Exempt from the requirements in this paragraph **are sterile preparations** compounded on a one-time basis for administration within seventy-two (72) hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with **standards for "Redispensed CSPs"** found in Chapter 797 of the United States Pharmacopeia- National Formulary (USP37-NF32) Through 2nd Supplement {37th Revision, Effective December 1, 2014), hereby incorporated by reference.	Reject: Does not apply to all sections.
1735.3(a)(1)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommend changing 1735.3 (a) (1) to read: "A reference to the applicable version of the master formula." Rationale: for consistency, master formula documentation is often maintained centrally in electronic records or locally in bound volumes. Requiring duplication on the compounding record is unnecessary. A master formula may be changed periodically and the compounding record should reference the version used for that particular preparation	Reject: Needs to be maintained in record
1735.3(a)(1)	California Society of Health-System Pharmacists Dawn Benton	Recommend changing 1735.3 (a) (1) to read: "A reference to the applicable version of the master formula." Rationale: for consistency, master formula documentation is often maintained centrally in electronic records or locally in bound volumes. Requiring duplication on the compounding record is unnecessary.	Reject: Needs to be maintained in record
1735.3(a)(6)	Cedars-Sinai Katherine Palmer Rita Shane	Recommended changes are to ensure consistency with beyond use dating specified in 1751.8 (p32). Additionally,USP 797 does not require this documentation for low and medium risk sterile to sterile preparations	Reject: This information is needed for all compounds.
1735.3(a)(10)	Sutter Health Jeannette Hanni	Recommend removing the documentation for storage of the drug preparation from 1735.3(a)(10) and adding this to section 1735.2(e) to be included as a requirement for the master formula record for the drug preparation Storage requirements for the compounded drug preparation should be consistent each time it is compounded or batch prepared and included in the master formula record.	Agreed: Language updated
1735.3(a)(10)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommend removing the documentation for storage of the drug preparation from 1735.3(a)(10) and adding this to section 1735.2(e) to be included as a requirement for the master formula record for the drug preparation. Rationale: Storage requirements for the compounded drug preparation should be consistent each time it is compounded or batch prepared and included in the master formula.	Agreed: Language updated
1735.3(a)(10)	California Society of Health-System Pharmacists Dawn Benton	Recommend removing the documentation for storage of the drug preparation from 1735.3(a)(10) and adding this to section 1735.2(e) to be included as a requirement for the master formula record for the drug preparation. Rationale: Storage requirements for the compounded drug preparation should be consistent each time it is compounded or batch prepared and included in the master formula.	Agreed: Language updated
1735.3(a)(10)	BJ Bartleson, RN, MS, NEA-BC California Hospital Association	Recommend removing the documentation for storage of the drug preparation from 1735.3(a)(10) and adding this to section 1735.2(e) to be included as a requirement for the master formula record for the drug preparation. Storage requirements for the compounded drug preparation should be compounded or batch prepared and included in the master formula record	Agreed: Language updated
1735.3(a)(10)	Providence Heath & Services Southern California Region	Providence recommends removing the documentation for storage of the drug preparation from 1735.3(a)(10) and adding this to section 1735.2(e) to be included as a requirement for the master formula record for the drug preparation. Storage requirements for the compounded drug preparation should be consistent each time it is compounded or batch prepared and included in the master formula record.	Agreed: Language updated
1735.3(c)	California Society of Health-System Pharmacists Dawn Benton	Recommend changing "FDA registered supplier" to "reliable supplier." Rationale: Many ingredients, including pharmaceutical ingredients, are not registered with the FDA. For example, many OTC ingredients.	Disagree, all active pharmaceutical ingredients need to be from an FDA registered supplier. The next sentence allows for other items from non-FDA registered suppliers

Code Section	Commenter	Comment	Board Response
1735.3(c)	California Pharmacist Association Brian Warren	The proposed changes to Section 1735.3, relating to recordkeeping, among other things, require suppliers of chemicals, bulk drug substances, and drug products to be FDA-registered, and strike an existing provision in subdivision (c) that states "certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration." We believe that this sentence should not be stricken from subdivision (c). The Board has stated that this change is necessary to "ensure that the supplier of drug products are adequately regulated by the Food and Drug Administration (FDA) and addressed the problem of the integrity of the purchased drug products by compounders providing compounded drug products to California consumers," and to "ensure a consolidated record for a compounded drug product that may have multiple ingredients from multiple FDA-registered suppliers." However, for drug products approved by the FDA, the FDA is the regulator of those products and responsible for ensuring that manufacturers ensure their products meet specification. (c) Active pharmaceutical ingredients shall be obtained from a FDA registered supplier. All other chemicals, bulk drug substances, and drug products, and components used to compound drug products preparations shall be obtained, whenever possible, from reliable FDA-registered suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, and bulk drug substances, drug products, and components used in compounding. **Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration**. Certificate s of purity or analysis are not required for drug products that are approved by the Food and Drug Administration. Certificates of purity or analysis, if available, are to be matched to the product received.	Agreed: Language updated
1735.4	Charles A. Reynolds, Pharm.D., B.C.P.P UCLA Health System	Is this applicable for IV solution labels compounded for inpatients?	Yes, no exceptions noted
1735.4(a)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommend revising to be consistent with recent discussions by the Board regarding B&P code 4076). Rationale: Labeling with trade names has been identified as a safety factor for prescription labels to prevent duplication of therapy and other adverse events.	Agreed: Language updated
1735.4(a)	California Society of Health-System Pharmacists Dawn Benton	Recommend revising to be consisted with recent discussions by the Board regarding B&P code 4076). Rationale: Labeling with trade names has been identified as a safety factor for prescription labels to prevent duplication of therapy and other adverse events.	Agreed: Language updated
1735.4(a)	San Mateo Medical Center Gary L. Horne, Director of Pharmacy	Consider changing generic to either brand or generic. This is because some hospital pharmacy systems may use the brand name of drug products for clarity for the nursing staff who will be asministering CSP.	Agreed: Language updated
1735.4(b)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommend deleting "or on the receipt". Rationale: Since this provision only applies to what is provided to the PATIENT (or patient's representative" ,for consistency with consumer and provider concern about knowing whether a compounded preparation is FDA approved, the statement should be provided on the label. The patient or provider may never see a receipt.	Agreed: Language updated
1735.4(b)	California Society of Health-System Pharmacists Dawn Benton	Recommend deleting "or on the receipt". Rationale: Consistency with consumer concern about knowing whether a compounded preparation is FDA approved.	Agreed: Language updated

Code Section	Commenter	Comment	Board Response
1735.4(b)	San Mateo Medical Center Gary L. Horne, Director of Pharmacy	Exempt from the requirements in this paragraph are sterile preparations compounded on a one-time basis for administration within seventy-two (72) hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia- National Formulary (USP37-NF32) Through 2nd Supplement {37th Revision, Effective December 1, 2014), hereby incorporated by reference.	Agreed: Language updated
1735.4(b)	GrayMatter Pharmacy Services, Inc Michael Moore, R.Ph.	This section should be modified to exclude compounded sterile products prepared by inpatient pharmacies. Once again we see another discrepancy between what should happen with “compounding pharmacies” and in-patient hospital pharmacies. This is too broad a brush to paint the whole industry and inspectors are not following the spirit of this intended language.	Agreed: Language updated
1735.4(c)	Sutter Health Jeannette Hanni	Recommend adding, "if the container is too small to add the facility label, the facility label may be placed on the overwrap"	Disagree: Overwrap will not help if the administering facility or patient has already started using the product when an issue occurs. There would be no way to track the drug to the compounder.
1735.4(c)	California Society of Health-System Pharmacists Dawn Benton	Recommend adding “if the container is too small to add the facility label, the facility label may be placed on the overwrap.” Rationale: To accommodate unit dose and other small packages of compounded products.	Disagree: Overwrap will not help if the administering facility or patient has already started using the product when an issue occurs. There would be no way to track the drug to the compounder.
1735.4(c)	California Pharmacist Association Brian Warren	We recommend the following modification to Section 1735.4 (c): Add: Drug preparations compounded into unit-dose containers that are too small for full compliance with subdivisions (a) and (b) are exempt from any minimum font size requirements in this Division.	Reject: Not address in the regulation
1735.4(c)	BJ Bartleson, RN, MS, NEA-BC California Hospital Association	Recommend adding”, if the container is too small to add the facility label, the facility label may be placed on the overwrap”	Disagree: Overwrap will not help if the administering facility or patient has already started using the product when an issue occurs. There would be no way to track the drug to the compounder.
1735.4(c)	San Mateo Medical Center Gary L. Horne, Director of Pharmacy	Exempt from the requirements in this paragraph are sterile preparations compounded on a one-time basis for administration within seventy-two (72) hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia- National Formulary (USP37-NF32) Through 2nd Supplement {37th Revision, Effective December 1, 2014), hereby incorporated by reference.	Reject: All compounded products need to be labeled.
1735.5	Charles A. Reynolds, Pharm.D., B.C.P.P UCLA Health System	The policy and procedure requirements are in two sections of the regulations each having some of the same requirements and some different. It makes it extremely difficult to understand and comply with all aspects when they are found in different locations in the law	Reject: 1735.5 is general compounding and 1751.3 is sterile.
1735.5	Douglas Barcon, Pharm.D., Barcon & Associates	Suggest adding new paragraph after (c) (11): (12) Policies and procedures regarding ensuring appropriate relative humidity in the compounding areas for sterile injectable preparations, and actions to take regarding any out of range relative humidity variations.	Reject: Humidity should not be an issue in the compounding area.
1735.5(a)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	*The Pharmacy shall follow its policies and procedures. Failure to follow these policies and procedures shall constitute grounds for disciplinary action.* Comment regarding section underlined: Thank you for reviewing and considering the feedback provided for the previous proposed revisions to 1735.5(a). Modification of the previously proposed changes “failure to follow these policies and procedures shall be deemed unprofessional conduct” to what is being proposed “Failure to follow these policies and procedures shall constitute grounds for disciplinary action.” is a much appreciated step in the right direction. Please consider further modification to adopt language that is more in line with ”Just Culture”. This would benefit patient safety by encouraging a strong culture of safety. Currently proposed changes do not provide latitude for minor policy and procedure deviations; which bear no reasonable risks to the patient. If approved as proposed, there may be unintended consequences such as reduced error reporting and creation of policy and procedures that are not specific enough to guide preparation or other aspects of compounding.	Reject: A PHY/LSC write the P&P and they need to be following them.

Code Section	Commenter	Comment	Board Response
1735.5(c)(2)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	Considering clarifying in a FAQ or revising the language. Many facilities maintain “evidence of staff education and training” in a staff competency file or in employees individual personnel record and not actually in the policy and procedures manual. Would it be permitted to have a policy in your manual that references there must be evidence of education and training, and where that evidence is located?	Reject: This is a recommendation for an FAQ not specifically a recommendation for change to regulation.
1735.5(c)(4)	Charles A. Reynolds, Pharm.D., B.C.P.P UCLA Health System	There is a problem with doing this for one time first dose sterile to sterile compounding. There is no way to validate these products by this definition since the product is made and used on the patient and therefore is not available for validation. This illustrates a problem with the regulations as the statements often are only applicable to compounding pharmacies that are compounding batches – not to hospital pharmacies that are compounding a single product for a patient. The regulations should be separated into two distinct sections – one for compounding pharmacies and one for hospital pharmacies.	Reject: This is a reference to P&P contents, and one time dose sterile to sterile procedures can be included in the P&P
1735.5(c)(6)	Community Regional Medical Center Bruce Lepley, Director of Pharmacy	Reason for Concern: For hospital pharmacies using only sterile FDA approved products for compounded sterile products we are ensuring that the product contains the appropriate amount of active ingredient. In addition, we are not successful in finding any laboratories in our area that can assay products to determine the amount (e.g. milligrams) of active ingredient in a compounded sterile product. Many laboratories use liquid chromatography-mass spectrometry (LCMS) that uses mass analysis and physical separation techniques to determine if a substance displays the same LCMS properties as a reference compound. This assay does not determine for instance a milligram amount of a substance in a compounded product so it would not meet the proposed regulation. Solution: Remove “potency” from the “integrity” definition and remove the requirement of the pharmacy determining, maintaining, validating and monitoring potency for compounded products if the source of the CSP’s come from sterile FDA approved products.	Agreed: Language updated
1735.5(c)(8)	BJ Bartleson, RN, MS, NEA-BC California Hospital Association	Recommend additional language at end after “pharmacist-in-charge” “or other evidence that each policy and procedure has been reviewed annually.”	Reject: We want the PIC to review them at least annually, the regulation needs to hold the PIC accountable to review them at least annually and document that.
1735.5(c)(8)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommend editing to read “Dates of annual reviews of the policy and procedure manual by the pharmacist-in-charge, signed and dated by the pharmacist-in-charge or other evidence that each policy and procedure has been reviewed annually.”. Rationale: Records of policy and procedure review and modification are often kept electronically to facilitate access by all pharmacy personnel and accreditation and regulatory surveyors.	Reject: We want the PIC to review them at least annually, the regulation needs to hold the PIC accountable to review them at least annually and document that.
1735.5(c)(8)	Sutter Health Jeannette Hanni	Recommend additional language: "...by the pharmacist in charge or other evidence that each policy and procedure has been reviewed annually.	Reject: We want the PIC to review them at least annually, the regulation needs to hold the PIC accountable to review them at least annually and document that.
1735.5(c)(8)	California Society of Health-System Pharmacists Dawn Benton	Recommend editing (8) to read “Dates of annual reviews of the policy and procedure manual by the pharmacist-in-charge, signed and dated by the pharmacist-in-charge or other evidence that each policy and procedure has been reviewed annually.” Rationale: Records of policy and procedure review and modification are often kept electronically to facilitate access by all pharmacy personnel and accreditation and regulatory surveyors.	Reject: We want the PIC to review them at least annually, the regulation needs to hold the PIC accountable to review them at least annually and document that.
1735.5(c)(8)	California Society of Health-System Pharmacists Dawn Benton	Recommend adding “in the pharmacy” at the very end. Would read: “Policies and procedures for storage of compounded sterile drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures in the pharmacy.” Rationale: To clarify which refrigerators to mean only those in the pharmacy.	Agreed: Language updated
1735.5(c)(10)	Sutter Health Jeannette Hanni	Recommend adding the qualifying language from USP 797 to consistently align with the national standards.	Reject: Unclear what language the commentor wants.

Code Section	Commenter	Comment	Board Response
1735.5(c)(10)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	1. Recommend adding "in the pharmacy" at the very end. Would read: "Policies and procedures for storage of compounded sterile drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures in the pharmacy." Rationale: To clarify which refrigerators to mean only those in the pharmacy. 2. Recommendation: Add language that supports the use of methods other than daily logs. "Policies and procedures for storage of compounded sterile drug preparations in the pharmacy and daily documentation of room, refrigerator, and freezer temperatures, through the use of paper logs or continuous temperature monitoring devices with appropriate alarms/alerts. Rationale: This language, particularly the phrase "daily documentation" could be interpreted to mean that only paper logs would be acceptable. Continuous electronic monitoring technology is at least as good as, if not superior to, manual documentation on paper logs	1. Agreed: Language updated 2. Rejected: Proposed language does not reference "logs"
1735.5(c)(10)	Douglas Barcon, Pharm.D., Barcon & Associates	After temperatures, delete the period and add "; and relative humidity in the compounding areas." Relative humidity is specified in 1751.3 (d)(3)(L) and 1751.4 (j).	Reject: Removed reference to "Humidity" from language
1735.5(c)(10)	Providence Heath & Services Southern California Region 20555 Earl Street Torrance, CA 90503	Policies and procedures for storage of compounded sterile drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures. If the compounding facility uses a continuous temperature recording device, compounding personnel shall verify at least once daily that the recording device itself is functioning properly. Providence recommends adding the qualifying language from USP 797 to consistently align with the national standards. Our refrigeration units provide continuous temperature monitoring and alert systems. Daily documentation would not provide an advantage to this 24/7monitoring nor does it increase patient safety beyond the systems already in place.	Rejected: Proposed language does not reference "logs". How they monitor "DAILY" can be referenced in their P&P.
1735.6(c)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	Consider deleting the words "in writing". This will allow pharmacies to maintain their records electronically if they choose. In addition, our automated compounding device (BAXA EM 2400) requires calibration; which once completed, generates a printed report of the calibration. Would this documentation be considered a record of calibration "in writing"?	Agreed: Language updated
1735.7(a)	The Institute for Community Pharmacy John Cronin	Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding. **"Training" as used in this subsection may include practice experience in the types of compounding in which the pharmacy personnel will be involved.**	Reject: Training definition is broad, and must be documented by the PIC and pharmacy
1735.8	San Mateo Medical Center Gary L. Horne, Director of Pharmacy	The language in this section is problematic in that the interpretation has been that any and all compounded products must be tested for "integrity, and ensure the integrity, potency, quality, and labeled strength". While this is a requirement for manufacturing, unless the pharmacy is compounding batches intended for future use, the actual testing for integrity, potency, quality, and labeled strength for every preparation compounded by the pharmacy creates not only operational and financial burdens, there is no scientific rationale. If a pharmacy routinely compounds a non-sterile product for immediate dispensing or, such as in a hospital, the pharmacy compounds sterile products for immediate use, testing samples of these products will only provide the results for that one preparation. In other words, if you test one sample, you know the results of one sample. Also, there are many compounded products (sterile and non-sterile) for which no laboratory test exists. It is clear that having policies, procedures, training and competency assessment to validate and ensure that personnel involved in compounding are competent to do so is the appropriate method to ensure the integrity, potency, quality, and labeled strength of compounded drug preparations. The existing and proposed language intentionally omits "laboratory testing is required for all products" because the intent of the regulations was to have proper policies, procedures, training and competency assessment to validate and ensure that personnel involved in compounding are competent. Furthermore, it is the process validation that ensures the integrity of the product.	Reject: Use of a Quality Assurance Plan will resolve

Code Section	Commenter	Comment	Board Response
1735.8	GrayMatter Pharmacy Services, Inc Michael Moore, R.Ph.	While much of this section remains unchanged, I have concerns about creating such a vague requirement to monitor quantitative accuracy. I believe that this section should be approached from two different perspectives. 1) From the perspective of the facility – a facility should show that its equipment is working appropriately and accurately. For example, if I am using a TPN compounder and a batch pump samples should be made to ensure that these pieces of equipment are working according to expectation. 2) more importantly – individuals compounding should be performing their activities accurately as well. We have a requirement to validate aseptic technique but no requirement exists to substantiate competence at quantitative compounding. If the board believes this should be monitored, then a specific requirement should be listed in the regulations. "Minimum standards" should be spelled out as well. We need guidance for what will be acceptable to the board with consistency. I don't want one inspect to come in and tell me 10% error is acceptable only to have another inspector the following year tell me it needs to be 5%. With all this said, I find it difficult to find a need for this section of the regulations. At most I might be able to understand the need for #1 above (facility testing).	Reject: USP sets a standard of 10% variance and I don't think the BOP need to put that in regulation because there will be time when a 10% is not acceptable (hydromorphone, TPA, PO heart medication/blood thinners).
35.8(a) and (c) and	Community Regional Medical Center Bruce Lepley, Director of Pharmacy	Reason for Concern: For hospital pharmacies using only sterile FDA approved products for compounded sterile products we are ensuring that the product contains the appropriate amount of active ingredient. In addition, we are not successful in finding any laboratories in our area that can assay products to determine the amount (e.g. milligrams) of active ingredient in a compounded sterile product. Many laboratories use liquid chromatography-mass spectrometry (LCMS) that uses mass analysis and physical separation techniques to determine if a substance displays the same LCMS properties as a reference compound. This assay does not determine for instance a milligram amount of a substance in a compounded product so it would not meet the proposed regulation. Solution: Remove "potency" from the "integrity" definition and remove the requirement of the pharmacy determining, maintaining, validating and monitoring potency for compounded products if the source of the CSP's come from sterile FDA approved products.	Reject: Policy and Procedure will resolve
1735.8(c)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommendation: Add language between the first and second sentences of 1735.8 (c) to clarify the exact requirements related to the quality assurance plan: "The criteria by which preparations would be tested for potency, quantitative analysis, and labeled strength analysis shall be described in the quality assurance plan. Rationale: This language could be interpreted to require that quantitative and qualitative analysis be performed on all compounded products regardless of cost, availability of the actual assay, or scientific validity. It has been our experience that some Board of Pharmacy inspectors have interpreted this language to require end product potency testing during of all pharmacy-compounded products. KP and many pharmacy professionals disagree with those requirements as they are inconsistent with the intent and provisions of the regulation 1735, et. seq. Pharmacies are compliant with 1735.8(c) if they have a PLAN that includes the elements mentioned above. Quantitative and qualitative laboratory type testing is not required unless specified for each product in our policies and procedures generally or by category - or in the Master Formula for a particular product. Test records of tests only have to be retained if such test was done either as a matter of policy or pursuant to an investigation after the raising of a quality concern for particular compounded preparation or a batch of a compounded preparation.	Reject: Use of a Quality Assurance Plan will resolve
1735.8(e)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommendation: Delete the words "including for preparations furnished to patient care areas," or define the term patient care area in Section 1735.1 Rationale: The proposed language "including for preparations furnished to patient care areas" is ambiguous. An outpatient Physician's office can be considered a patient care area. The current language would require the pharmacy to be responsible for monitoring the storage temperatures after the preparation has been sold/transferred to a Physician's office.	Agreed: Language updated

Code Section	Commenter	Comment	Board Response
1735.8(e)	California Society of Health-System Pharmacists Dawn Benton	Recommend deleting "including for preparations furnished to patient care areas". Rationale: Other than for patient care areas in a hospital, the compounding pharmacy is not authorized or responsible for medication storage such as compounded preparations furnished to a prescribers office.	Agreed: Language updated
1751	California Pharmacist Association Brian Warren	First, we recommend modification of these proposed regulations to include an exemption of emergency eye-rinsing stations from the prohibition on sinks. Second, because air quality standards for buffer areas and PECs are already present in Section 1735.1, we recommend striking the reference to the ISO classes in this section. Removing these references has no legal impact on this section but makes it easier to comprehend. (3) A sink shall be included in accordance with Section 1250 of Title 24, Part 2, of the California Code of Regulations. Sinks and drains shall not be present in ~~an ISO Class 7 or better~~ a buffer area, nor within three feet of ~~an ISO Class 5~~ a PEC located in a segregated compounding areas, **with the exception of emergency eye-rinsing stations**. A sink may be located in an ante-area.	Agreed: Language updated
1751	Charles A. Reynolds, Pharm.D., B.C.P.P UCLA Health System	This part of the regulation does not take into consideration that on a Satellite Pharmacy (a non USP 797 cleanroom) the designated compounding and segregated compounding area are the same thing. (See comments in 1735.1q) An ISO Class 5 laminar airflow hood is both of these and needs to be recognized within the regulation. In current clinical practice first doses [sterile to sterile compounding] made in such an environment meet all required sterility issues for patient care. As such the environmental requirements should actually apply only to the compounding area within the laminar airflow hood not the pharmacy satellite environment. As written this would forbid the compounding of any product outside a USP797 compliant compounding area which would basically negate one of the basic tenants of Satellite Pharmacies which is the ability to compound first dose intravenous products in an ISO5 laminar airflow hood. It will return clinical practice to bedside compounding by nurses, a proven risky practice to patients. Again, 1751.1 Recordkeeping Requirements assumes that compounding is done in a USP 797 clean room as these records would not apply to compounding done for immediate first doses in a Satellite Pharmacy.	Agreed: Refer to 1751.8(f)
1751(b)(3)	Charles A. Reynolds, Pharm.D., B.C.P.P UCLA Health System	It may not be possible to move an existing PEC or sink that is currently within three feet of each other in a pharmacy satellite without major construction that would disrupt patient care. Are there any exceptions to this regulation (e.g., if there is a physical barrier/wall between the PEC and sink)?	Reject: No exception, patient safety first. Sinks are dirty and do not belong in the ISO 7 or by an ISO 5
1751(b)(3)	Community Regional Medical Center Bruce Lepley, Director of Pharmacy	Reason for Concern: Many hospitals have established pharmacy satellites nearby patient care areas to serve our most vulnerable patients (e.g. Intensive Care Units).The central pharmacy is too far from these patient care areas and the pharmacy satellites provide a venue to provide patient care that is closer to the patients. These pharmacy satellites are one room that provides a place for the pharmacy to perform order verification, drug storage, and drug preparation. Many of the pharmacy satellites have very limited room, thus the pharmacy will place compounding aseptic containment isolators (CACIs) which are enclosed to the surrounding environment and should have evidence from the manufacturer that they meet USP chapter 797 and Controlled Environment Testing Association (CETA) requirements. We believe that we can remove the 3 foot no sink/drain requirement when CACI's are used to support pharmacy satellites. The alternative would be to close these pharmacy satellites that do not have the room to abide by the 3 foot no sink/drain rule which is not consistent with a patient centered care model. Solution: Make an exception that if the ISO Class 5 PEC is a CACI, that the three foot sink/drain rule does not apply while maintaining that sinks and drains should not be placed in a buffer area or in ISO class 7 or better.	Reject: Information came from an unverified study
1751(b)(4)	Douglas Barcon, Pharm.D., Barcon & Associates	Suggest add at end: "Food shall not be stored in refrigerators and/or freezers designated for storage of such materials."	Reject: This should be part of pharmacies P&P as it applies to all medication refrigerators.

Code Section	Commenter	Comment	Board Response
1751.1(a)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommendation: Add language that supports the use of methods other than daily logs, for example, “daily documentation of room, refrigerator, and freezer temperatures, through the use of paper logs or continuous temperature monitoring devices with appropriate alarms/alerts. Rationale: This language, particularly the phrase “daily documentation” could be interpreted to mean that only paper logs would be acceptable. Continuous electronic monitoring technology is at least as good as, if not superior to, manual documentation on paper logs, Recommendation: Add language that supports the use of methods other than daily logs for air velocity, for example, “Daily documentation of air pressure differentials or air velocity between adjoining all ISO rooms or areas and measurement between all ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, through the use of paper logs or continuous monitoring devices with appropriate alarms/alerts.” Rationale: This language, particularly the phrase “daily documentation” could be interpreted to mean that only paper logs would be acceptable. Continuous electronic monitoring technology is at least as good as, if not superior to, manual documentation on paper logs or continuous monitoring devices with appropriate alarms/alerts.”	Rejected: Proposed language does not reference "logs". How they monitor "DAILY" can be referenced in their P&P.
1751.1(a)(3)	Hartley Medical, William Stuart	a. Comment: I am asking the board to clarify the intention of performing fingertip testing in association with media fill testing. It is our perception that fingertip testing provides useful information, but does not demonstrate a lack of aseptic technique. At my institution we have performed fingertip assessment during media fills, and as of this date have yet to detect a media fill failure in association with detecting colony forming units upon fingertips. b. Recommendation: I recommend removing fingertip assessment after media fill test.	Reject: Testing is required
1751.1(a)(5)	California Society of Health-System Pharmacists Dawn Benton	Recommend allowing continuous temperature monitoring. Rationale: Current technology is often used for electronic monitoring and alerting regarding temperature ranges.	Rejected: Proposed language does not reference "logs". How they monitor "DAILY" can be referenced in their P&P.
1751.1(a)(5)	Douglas Barcon, Pharm.D., Barcon & Associates	Suggest following change: (a)(5) Daily documentation of room HUMIDITY consistent with 1751.4 (j), AND~~,~~ refrigerator~~,~~ and freezer temperatures appropriate for drug preparations consistent with the temperatures listed in section 1735.1 for:	Reject: USP 797 does not require daily humidity monitoring
1751.1(a)(5)	Providence Heath & Services Southern California Region	Add to section 1751.1(a)(S): If the compounding facility uses a continuous temperature recording device, compounding personnel shall verify at least once daily that the recording device itself is functioning properly. As noted for 1735.5(c)(10), Providence recommends adding the qualifying language from USP 797 to consistently align with the national standards. Our refrigeration units provide continuous temperature monitoring and alert systems. Daily documentation would not provide an advantage to this 24/7monitoring nor does it increase patient safety beyond the systems already in place.	Rejected: Proposed language does not reference "logs". How they monitor "DAILY" can be referenced in their P&P.
1751.1(a)(7)	California Society of Health-System Pharmacists Dawn Benton	Recommend allowing continuous airflow monitoring. Rationale: Current technology is often used for electronic monitoring and alerting regarding airflow ranges.	Reject: Language is not disallowing electronic monitoring as long as it is documented daily.
1751.1(a)(7)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	I am not aware of a device that can be placed in an area to determine on a daily basis (or continuously) the air velocity across a line of demarcation. A qualified technician as described in 1751.4 can determine the air velocity across the line of demarcation between an buffer and ante-area using special equipment they possess and are trained to use. Consider deleting the word “Daily” at the front of the sentence, and insert it after the word “differentials”. Consider inserting the words “every 6 months during clean room certification” after the word “velocity” or after the word “isolators” for readability.	Reject: Language states: air pressure differentials <u>or</u> air velocity.

Code Section	Commenter	Comment	Board Response
1751.1(a)(7)	Providence Heath & Services Southern California Region	Daily documentation of air pressure differentials, when applicable, or air velocity between all adjoining ISO rooms or areas and measurement between all ISO rooms or areas, including those associated with compounding aseptic (containment) isolators. Providence recommends including the wording "when applicable." This is because facilities without cleanrooms or buffer areas within anterooms cannot have pressure differentials so a log would not be required.	Reject: Language states: air pressure differentials or air velocity.
1751.1(a)(7)	Community Regional Medical Center Bruce Lepley, Director of Pharmacy	**Reason for Concern:** The language is repetitive and unclear ("adjoining all ISO" and "between all ISO"). The inclusion of compounding aseptic (containment) isolators is unclear as to what needs to be documented. **Solution:** Strike repetitive language and delete language on the requirement for CACIs.	Agreed: Language updated
1751.2(d)	Harbor Compounding Pharmacy Mai Tran and Sam Kitahara	The proposed language does not specifically define a hazardous drug, and because of the generalization, hazardous drugs can be defined as any hazardous drug defined by the NIOSH List of 2012, which can include antineoplastic, hormones, gonadotropins, oxytocics, antipyschotics, etc. We recommend that the proposed language be more specific by defining hazardous drugs as any drug that is considered an antineoplastic agent in the NIOSH List, or removing the term hazardous drug altogether and replace with antineoplastic drugs. Recommended language: "All antineoplastic agents shall bear a special label which states "chemotherapy - dispose of properly" if applicable." Or All hazardous agents shall bear a special label which states "Hazardous - dispose of properly" or "chemotherapy - dispose of properly" if applicable. A hazardous drug is any antineoplastic agent that is listed on the NIOSH List of Antineoplastic and Other Hazardous Drugs.	Agreed: Language updated
1751.3	Charles A. Reynolds, Pharm.D., B.C.P.P UCLA Health System	The policy and procedure requirements are in two sections of the regulations each having some of the same requirements and some different. It makes it extremely difficult to understand and comply with all aspects when they are found in different locations in the law	1735.3 are records that are required, and they are needed to ensure PHY/HSP have compounded in compliance with the regulations to ensure safe compounding for patient wellbeing
1751.3(a)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	Please consider deleting the word "written". This will allow pharmacies to maintain electronic policy and procedures, which are more easily retrievable. There are many facilities that are using systems to electronically store and track policy and procedure archiving, renewals, revisions, and due dates.	Reject: "Written" does not mean a hard written document
1751.3(a)(2)	Cedars-Sinai Katherine Palmer Rita Shane	Recommend exemption for requiring rate on the label for hospital patients since rates change multiple times per day based on the patient's condition (e.g. heparin,dopamine, nitroprusside). The medical record provides the most current order and therefore is the source of truth for the rate of administration.	Reject: Hospitals can state "titrate per protocol" as a recommended rate of adminsitration, if allowed in the hospital's P&P
1751.3(a)(7)	Charles A. Reynolds, Pharm.D., B.C.P.P UCLA Health System	Again impossible for first dose compounding in Pharmacy Satellites (non USP 797 cleanrooms) see 1735.5c4 comments.	Reject: Only asking for P&P about the sampling plan. It not stating when and were the samples are to be taken.
1751.3(b)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	Please consider deleting the word "in writing". This will allow pharmacies to maintain electronic master formula records, which are more easily retrievable.	Reject: "Written" does not mean a hard written document
1751.3(c)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	Please consider deleting the word "written". This will allow pharmacies to maintain electronic policy and procedures, which are more easily retrievable. There are many facilities that are using systems to electronically store and track policy and procedure archiving, renewals, revisions, and due dates.	Reject: "Written" does not mean a hard written document
1751.3(d)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	Please consider deleting the word "written". This will allow pharmacies to maintain electronic policy and procedures, which are more easily retrievable. There are many facilities that are using systems to electronically store and track policy and procedure archiving, renewals, revisions, and due dates.	Reject: "Written" does not mean a hard written document
1751.3(d)(1)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	Please consider deleting the word "written". This will allow pharmacies to maintain electronic policy and procedures, which are more easily retrievable. There are many facilities that are using systems to electronically store and track policy and procedure archiving, renewals, revisions, and due dates.	Reject: "Written" does not mean a hard written document

Code Section	Commenter	Comment	Board Response
1751.3(d)(2)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	Please consider deleting the word “written”. This will allow pharmacies to maintain electronic policy and procedures, which are more easily retrievable. There are many facilities that are using systems to electronically store and track policy and procedure archiving, renewals, revisions, and due dates.	Reject: "Written" does not mean a hard written document
1751.3(d)(3)(M)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	Consider changing the word “prevention” to “preventative”.	Agreed: Language updated
1751.3(d)(4)(B)(iii)	Sutter Health Jeannette Hanni	Current: "Appropriate sterility and bacterial endotoxin testing" Issue: No endotoxin testing required for sterile to sterile compounding. Recommend reverse B.iii with C.ii. Low-risk and medium-risk preparations would only require sterility testing if extended procedures beyond-use dating was being used.	Agreed: Language updated
1751.3(d)(4)(B)(iii)	California Society of Health-System Pharmacists Dawn Benton	Recommend deleting “and bacterial endotoxin”. Rationale: Endotoxin testing is not an industry standard for sterile to sterile preparations and should be reserved for nonsterile to sterile preparations	Agreed: Language updated
1751.3(d)(4)(B)(iii)	Cedars-Sinai Katherine Palmer Rita Shane	Adopt USP 797 which requires bacterial endotoxin (pyrogen) testing for non-sterile to sterile compounding.	Agreed: Language updated
1751.3(d)(4)(B)(iii)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommendation: “For sterile to sterile batch compounding: appropriate end product examination.” Rationale: According to USP Chapter 797, which is a National Standard, sterility and bacterial endotoxin testing is not routinely required for sterile to sterile batch compounding There are many common scenarios involving sterile to sterile transfers, where this requirement is inappropriate – e.g. compounding injectable antibiotics in hospitals; compounding nine day supplies of total parenteral nutrition solutions and injectable antibiotics for administration to patients at home. These are all low risk and medium risk preparations. The current language would require unnecessary testing and possibly delay therapy to patients. It has been our experience that some Board of Pharmacy inspectors are incorrectly interpreting “end product examination” to mean “end product testing”. We therefore believe it is necessary to define “end product examination” and have included that in the recommendations above to ensure it meets specifications.	Reject: these are the requirement of the P&P's and not a requirements to test.
1751.3(d)(4)(B)(iii)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	This subdivision requires a written policy and procedure regarding appropriate sterility and bacterial endotoxin testing but does this subdivision require a facility to actually conduct these validations if the facility is not doing “high risk” compounding and is not exceeding USP 797 BUDs? If so, I would like to raise a concern that **sterile “batch” compounding** in accordance with the proposed definition outlined in 1735.1(b) may not warrant tests for sterility or bacterial endotoxins. Please strongly consider revising this language so it is more in line with USP 797. For example, sterility testing is warranted in circumstances that the assigned BUD exceeds the timeframes specified in the proposed sections of 1751.8. Endotoxin testing warranted for “high risk” in the circumstances described in USP 797. If a batch consists of two doses, the testing would not be possible without destroying all of the finished preparation.	Agreed: Language updated
1751.3(d)(4)(B)(iii)	BJ Bartleson, RN, MS, NEA-BC California Hospital Association	Currently states, “Appropriate sterility and bacterial endotoxin testing”, no endotoxin testing required for sterile to sterile compounding. Recommend reverse B.iii with C.ii. Low risk and medium risk preparation would only require testing if extended beyond use dating was being used.	Agreed: Language updated

Code Section	Commenter	Comment	Board Response
1751.3(d)(4)(B)(iii)	Charles A. Reynolds, Pharm.D., B.C.P.P UCLA Health System	For sterile to sterile batch compounding, sterility and bacterial endotoxin testing would not be practical for preparations with a short BUD (e.g. 24 hours). The preparations would be dispensed and administered long before the results of the tests. The compounding pharmacy would ensure sterility of the product through use of aseptic technique, proper hand hygiene/garbing, and compounding within a certified ISO Class 5 PEC. Sterility and bacterial endotoxin testing should only be required for preparations given a BUD longer than recommended by USP 797.	Reject: these are the requirement of the P&P's and not a requirements to test.
1751.3(d)(4)(B)(iii)	Community Regional Medical Center Bruce Lepley, Director of Pharmacy	**Reason for Concern:** This section addresses sterile to sterile batch compounding and bacterial endotoxin testing is only mentioned in the context of non-sterile to sterile compounding in USP <797>. While sterility testing may be performed in the pharmacy, bacterial endotoxin testing will need to be sent to an outside facility. This may pose an access issue due to limited numbers of labs available for this procedure as well as a financial burden. Bacterial endotoxin testing may not provide useful information to the pharmacy due to the delay in test results. Solution: Delete “bacterial endotoxin.”	Agreed: Language updated
1751.3(d)(4)(B)(iii)	Providence Heath & Services Southern California Region	Remove sterility and endotoxin testing verbiage from 1751.3(d)(4)(B)(iii) and add itto 1751.3(d)(4)(C) section on non-sterile to sterile compounding: * USP 797 guidelines require sterility and bacterial endotoxin testing only for high-risk level (i.e. non-sterile to sterile) compounding prepared in groups of more than 25 individual single-dose packages. * Low-risk and medium-risk preparations would only require sterility testing if extended beyond- use dating was being used per USP 797.	Agreed: Language updated
1751.3(d)(4)(C)(ii)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommendation: Use the term “end-product examination” as defined above and add to this sub-section regarding non-sterile to sterile batch compounding “Passing the sterility test in accordance with methodologies and processes found in Chapter 71 of the United States Pharmacopeia-National Formulary (USP37-NF32) through 2nd Supplement (37th Revision, Effective December 1, 2014), and testing for pyrogens in accordance with the methods of Chapter 85 and 151 of the United States Pharmacopeia – National Formulary (USP37-NF32) through 2nd Supplement (37th Revisions, Effective December 1, 2014), hereby incorporated by reference.” Rationale: According to USP Chapter 797, End Product Sterility and bacterial endotoxin testing is required for non-sterile to sterile batch compounding.	Reject: However, language has been updated to remove endotoxin testing
1751.3(d)(4)(L)	Providence Heath & Services Southern California Region	Providence requests definition of acceptable humidity levels for controlled storage areas. Humidity level for the compounding area is defined in Section 1751.4(j) however, humidity level for the controlled storage area is not specified elsewhere.	Reject: USP 797 does not require daily humidity monitoring
751.4(d) and (d)(2	Douglas Barcon, Pharm.D., Barcon & Associates	Suggest adding “and drug” after word “batch” and before semicolon in (d)(2). Optionally could add “after each change of drug” as individual line and renumber, or not make change and assume compounder would interpret (d)(4) to include a drug change. Rationale: For example a multi-dose piperacillin/tazobactam infusion bag is compounded and then is followed by a potassium phosphate infusion bag. Cleaning would prevent possible penicillin cross contamination.	Reject: Language changed and Batch definition changed.
1751.4(d)(2)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommend remove subsection (2). Rationale: Inconsistent with industry standards and hospital practice under the proposed definition of a “batch”.	Reject: Language changed and Batch definition changed.
1751.4(d)(2)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	Cleaning and disinfecting surfaces of the ISO Class 5 PEC before and each batch may be an unreasonable frequency and would be a significant operational impact considering how SBOP is proposing to define “batch”.	Reject: Language changed and Batch definition changed.

Code Section	Commenter	Comment	Board Response
1751.4(d)(2)	California Society of Health-System Pharmacists Dawn Benton	Recommend remove subsection (2). Rationale: Inconsistent with industry standards and hospital practice under the proposed definition of a “batch”.	Reject: Language changed and Batch definition changed.
1751.4(e)	Cedars-Sinai Katherine Palmer Rita Shane	Sterile alcohol is not recommended for cleaning floors by USP 797 due to the potential for flammability and increasing the risk of employee injuries due to falls. Germicidal agents alone are recommended for disinfecting floors,and germicidal agents in combination with sterile isopropyl alcohol are recommended for critical work surfaces (such as the inside of hoods).	Agreed: Language updated
1751.4(e)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommend replacing with: “Counters, tables, and cleanable work surfaces shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent (e.g., sterile isopropyl alcohol) daily.. Floors shall be cleaned with a germicidal detergent and water daily Walls, ceilings, storage shelving, and stools shall be cleaned with a germicidal detergent and water monthly. Cleaning and disinfecting shall occur after any unanticipated event that could increase the risk of contamination. Rationale Cleaning large surgace areas, such as floors and walls, etc. with Isopropyl alcohol, which is highly flammable, can create a substantial fire hazard which would be especially dangerous in hospitals and patient care areas. Using “sterile isopropyl alcohol” widely is also very costly without justification for certain surfaces. Daily cleaning of floors with a non-flammable agent is reasonable.	Agreed: Language updated
1751.4(e)	California Society of Health-System Pharmacists Dawn Benton	Recommend replacing with: Counters, tables, and cleanable work surfaces shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent (e.g., sterile isopropyl alcohol) daily. Floors shall be cleaned with a germicidal detergent and water daily walls, ceilings, storage shelving, and stools shall be cleaned with a germicidal detergent and water monthly. Cleaning and disinfecting shall occur after any unanticipated event that could increase the risk of contamination Rationale: The use of large amounts of isopropyl alcohol is impractical and can become a fire hazard. (See the CDC’s website on disinfecting the healthcare environment. http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf)	Agreed: Language updated
1751.4(e)	Charles A. Reynolds, Pharm.D., B.C.P.P UCLA Health System	Such rigorous cleaning should not be required for non-cleanroom areas such as pharmacy satellites. These areas are not controlled environments and do not provide ISO Class 8 air or better. In other words, they are not sterile environments and should not be cleaned as if they are sterile environments. In these areas, compounding is performed only for urgent, first dose preparations. Cleaning/disinfection should be performed within the ISO Class 5 PEC, the only controlled area in a pharmacy satellite. The mentioned cleaning in 1751.4(e) should be enforced in controlled environments only. Separate cleaning procedures for non-ISO classified satellites are needed.	Reject: Just because its not an ISO environment does not mean it shouldn't be cleaned.
1751.4(e)	Central Admixture Pharmacy Services, Inc William Jones	Change the wording in section (e) to read: Counters, cleanable work surfaces and floors shall be cleaned with a germicidal agent and water and disinfect with a suitable agent. … Many pharmacies may be using a sporicidal agent followed by sterile isopropyl alcohol which may be superior to the method written in the proposal.	Agreed: Language updated
1751.4(e)	BJ Bartleson, RN, MS, NEA-BC California Hospital Association	Recommend the following language for increased clarification: “Counters, tables, and cleanable work surfaces shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent (e.g., sterile isopropyl alcohol) daily. Floors shall be cleaned with a germicidal detergent and water daily. Walls, ceilings, storage shelving, and stools shall be cleaned with a germicidal detergent and water monthly. Cleaning and disinfecting shall occur after any unanticipated event that could increase the risk of contamination.”	Agreed: Language updated
1751.4(e)	Douglas Barcon, Pharm.D., Barcon & Associates	Consider disinfection of floors and walls with disinfection agents other than sterile isopropyl alcohol in the e.g. example to prevent generation of large amounts of alcohol vapor in an enclosed space or keeping alcohol and adding alternative agents. Such alternative agents could include, quaternary ammonium disinfectants and 10% bleach based on surface compatibility.	Agreed: Language updated

Code Section	Commenter	Comment	Board Response
1751.4(e)	Scripps Health-contact Amy Benner	Recommend change in language to clarify cleaning agents to be used. Isopropyl alcohol should only be used on **work** surfaces (LAFW/BSC/CACI/CAI etc.), carts and counters. Cleaning the entire room with IPA would be a fire hazard. Also include the use of a sporicidal agent at least monthly to clean all areas. Specific language changes recommended as follows: Counters, and cleanable work surfaces (eg. LAFW) ~~and floors~~ shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent (eg. sterile isopropyl alcohol) daily. Floors shall be cleaned with a germicidal detergent daily. Walls, ceilings, storage shelving, tables and stools shall be cleaned with a germicidal detergent and ~~water and disinfected with a suitable agent (eg. Sterile isopropyl alcohol)~~ monthly. A cleaning agent with sporicidal properties shall be used at least once per month in place of the germicidal detergent on all surfaces.	Agreed: Language updated
1751.4(f)	California Pharmacist Association Brian Warren	(f) Pharmacies **shall compound** ~~preparing~~ sterile ~~compounded~~ preparations ~~require~~ **with** the use of a PEC that provides ISO Class 5 air or better. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-11, Revised January 31, 2012). Certification records must be retained for at least 3 years. Compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ~~ISO Class 7~~ a buffer area if the isolator meets the following criteria.	Reject: Changing text does not improve regulation
1751.4(g)	California Society of Health-System Pharmacists Dawn Benton	Recommend adding the following sentence after "regardless of whether the drug ingredients are considered hazardous.": "Unless the hazardous drug PEC is decontaminated before nonhazardous drugs are compounded in the same PEC. Rationale: In small oncology preparation environments that have only one PEC, it is impractical to decontaminate the PEC between compounding each oncology preparation. However, the environment should be decontaminated before compounding a nonhazardous preparation.	Reject: Decontamination doesn't always remove all by-products
1751.4(g)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommendation: Add an additional sentence to the proposed language: "…must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous. Unless the hazardous drug PEC is decontaminated before the non-hazardous drugs are compounded." Rationale: In small Oncology Pharmacies serving prescriber offices and clinics, that have only one primary engineering control, e.g. a biological safety cabinet, to compound hazardous and non-hazardous preparations, and if the hood is decontaminated between compounding hazardous and non-hazardous preparations, it would be appropriate to exclude the requirement to label non-hazardous drugs as "hazardous".	Reject: Decontamination doesn't always remove all by-products
1751.4(g)	California Pharmacist Association Brian Warren	During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene ~~and garbing~~ must occur, complete with ~~hair cover, facemask, beard cover (if applicable), polyprophylen or low shedding gown that closes in the back, shoe covers, and~~ two layers of gloves that have been tested to meet ASTM 6978-05 with the outermost glove that contacts the sterile drug preparation.	Reject: Garbing in Required
1751.4(g)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	The language regarding the gloves is confusing. Is it intended that the outermost glove that contacts the sterile drug preparation must have been tested to meet ASTM 6978-05? If so, it reads that both layers of gloves must have been tested to meet ASTM 6978-05.	Agreed: Language updated
1751.4(g)	Charles A. Reynolds, Pharm.D., B.C.P.P UCLA Health System	Clarification is needed if this is only required for ISO classified rooms. If this is also required for non-ISO classified rooms (e.g. pharmacy satellites), clarification is needed on the proper gowning procedure. The shoe covers are one of the first things donned since it is considered dirty. Hand hygiene would occur far from the segregated compounding area in a non-ISO classified room. If shoe covers are donned first, they would get dirty outside of the segregated compounding area. If shoe covers are donned last immediately outside the segregated compounding area the hands would get dirty again. Separate hand hygiene and garbing procedures for non-ISO classified satellites are needed.	Reject: Applies to all hazardous compounding

Code Section	Commenter	Comment	Board Response
1751.4(g)	UCSD Research Pharmacy Leticia Muttera, Pharm. D	? Unless rigorously decontaminated and a certain amount of time has passed between compounding hazardous and non-hazardous preparations. For those of us who do investigational agents and do extremely low volume, we often need to use the same PEC for both hazardous and non-hazardous. Labeling everything as hazardous may cause concern to subjects when their medications are labeled as hazardous when they are not. Often biohazards can be decontaminated using good hood cleaning techniques with acceptable cleansers and chemicals. Air and surface sampling perhaps can also serve as confirmation of decontamination.	Reject: Applies to all hazardous compounding
1751.4(g)	Charles A. Reynolds, Pharm.D., B.C.P.P UCLA Health System	This section is confusing because hazardous and non-hazardous compounding are both discussed in the same sections. Please separate out the regulations for hazardous and non-hazardous compounding. Labeling drugs that may have been compounded in a biological safety cabinet that was used to compound a hazardous drug as hazardous would be extremely confusing to the nursing staff that rely on the information on the label for their gowning/disposal procedures. We would have total confusion in the institution as to what products require hazardous precautions and what products do not should this regulation be followed. Instead of changing to labeling of products, the regulations should stress thorough decontamination and cleaning in between hazardous and non-hazardous compounding	Reject: Applies to all hazardous compounding
1751.4(g)	Providence Heath & Services Southern California Region	Pharmacies preparing sterile hazardous agents shall do so in accordance with Section ~~505.12.1~~ 505.5.1 of Title 24, Part 4, Chapter 5, of the California Code of Regulations. In 2010, the Building Standards Commission moved the sections applicable to *Pharmacies- Compounding Area of Parenteral Solutions* to Title 24, Part 4, Chapter 5, 505.5. Section 505.5.1addresses the hoods required for cytotoxic agents.	Agreed: Language updated
1751.4(g)	Providence Heath & Services Southern California Region	Recommend removing this from 1751.4(g) and adding this to section 1751.2 under Sterile Compounding Labeling Requirements as 1751.2(e). This requirement fits more consistently with the other labeling requirements including the hazardous sterile compounded preparation labeling requirements.	Reject: Maintain language as is
1751.4(g)	Providence Heath & Services Southern California Region	Recommend removing this from 1751.4(g) and adding this to section to 1751.5 Sterile Compounding Attire. This requirement builds upon the hazardous drug compounding attire requirements already listed in 1751.5(b) by including more details about which personal protective equipment must be used for all hazardous drug preparations in addition to a compounding aseptic containment isolator	Reject: Maintain language as is
1751.4(i)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommendation: Include the USP Chapter 797 definitions for medium risk-level and high risk-level compounding in the definitions section (1735.1). Adopt the language in USP Chapter 797 for the frequency of the sampling plan, e.g. “Environmental sampling shall occur as part a comprehensive quality management program and shall occur minimally under any of the following conditions: 1. As part of the commissioning and certification of new facilities and equipment 2. Following any servicing of facilities and equipment 3. As part of the re-certification of facilities and equipment, at least every 6 months 4. In response to identified problems with compounded preparation or staff technique 5. In response to issues with CSPs, observed compounding personnel work practices, or patient-related infections (where the CSP is being considered as a potential source of the infection).” Rationale: The definitions for medium risk level and high risk level compounding are not included in the definitions. The frequency of sampling is over burdensome and without merit scientifically.	Reject: Not using USP 797 definitions; however, the lanaguage has been modified.

Code Section	Commenter	Comment	Board Response
1751.4(i)	California Pharmacist Association Brian Warren	Viable surface sampling shall be done at least **quarterly** ~~monthly~~ for low and medium risk- level compounding and **monthly** ~~weekly~~ for high-risk compounding. Volumetric air sampling by impaction shall be done at least once every six months ~~for low and medium risk level compounding and weekly for high-risk compounding~~. Viable surface and volumetric air sampling shall be performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling. Viable air sampling is to be performed under dynamic conditions that simulate actual production. Surface sampling is to be performed under dynamic conditions of actual compounding. When the environmental monitoring action levels are exceeded, **as defined by [***]**, the pharmacy shall identify the CFUs at least to the genus level in addition to conducting an investigation. Remediation shall include an immediate investigation of cleaning and compounding operations and facility management. **As used in this subdivision, "low risk compounding," "medium risk compounding," and "high risk compounding " have the meanings defined in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference.**	Reject: Not using USP 797 definitions; however, the lanaguage has been modified.
1751.4(i)	California Society of Health-System Pharmacists Dawn Benton	Recommend including USP 797 definitions for medium and high risk compounding. Adopt the USP 797 standard for frequency of sampling environmental surfaces. Rationale: The proposed regulation provision is inconsistent with industry standard and hospital practice and is impractical and costly to implement.	Reject: Not using USP 797 definitions; however, the lanaguage has been modified.
1751.4(i)	GrayMatter Pharmacy Services, Inc Michael Moore, R.Ph.	You must define action levels. Is it 3 CFU's? 30? The state board has taken upon itself to micro-manage pharmacy compounding practices, so I do not understand why they are not specifying this number/level within the regulatory language.	Reject: The PHY is required to define the action level per 1751.3(d)(4)(D)
1751.4(i)	Charles A. Reynolds, Pharm.D., B.C.P.P UCLA Health System	Monthly and weekly testing is not required by USP 797, the professional standard for compounding sterile preparations. According to USP 797, air sampling is only required at least *semiannually*. For surface sampling USP 797 states that the sampling shall be performed on a *periodic basis*. Monthly and weekly testing would be in excess of what is needed (as compared to USP 797), and would come at a very high cost to the institution.	Reject: Not using USP 797 definitions; however, the lanaguage has been modified.
1751.4(i)	Hartley Medical, William Stuart	a. Comment (1): Surface and Volumetric air sampling on a weekly basis will impose a costly burden to compounding pharmacies involved with high risk compounding. The cost of air sampling devices range from $2000-$10,000 if an individual was to perform this themselves. The cost for an outside vendor to perform this test will range from $200-$500 per test and an additional cost for microbial identification. I strongly believe that environment monitoring is important to ensure a safe compounding environment. b. Comment (2): This regulations states that identification of the CFU, will occur upon test results exceeding action levels. There are two issues here. First is identification only occurs after an excursion beyond action levels. In a particular scenario, the test results may be below an action limit, however the organism may be objectionable such as Escherichia coli. Secondly, many organisms under certain genera are not pathogenic. For example, the genus of Staphylococcus contains many different species found normally on human skin(such as hominis, simulans, and capitis) pose no danger. The main species of clinical significance is Staphyloccocus aureus. Therefore identification of species is imperative. c. Recommendation (1): I am recommending for the committee to consider quarterly or monthly testing. d. Recommendation (2): Microbial identification to genus and species.	Reject: Not using USP 797 definitions; however, the lanaguage has been modified.
1751.4(i)	Douglas Barcon, Pharm.D., Barcon & Associates	Viable surface sampling post disinfection would be a process to validate the effectiveness of the disinfection process. Consider adding surface sampling post disinfection to the current surface sampling performed under dynamic compounding.	Reject: Extra testing requirement not
1751.4(i)	Providence Heath & Services Southern California Region 20555 Earl Street Torrance, CA 90509	Recommend removing 1751.4(i) and adding this verbiage to 1751.7 Sterile Compounding Quality Assurance and Process Validation. This requirement is part of quality assurance and process validation for the compounding environment.	Reject: The BOA says this is our requirement

Code Section	Commenter	Comment	Board Response
1751.4(i)	Providence Heath & Services Southern California Region 20555 Earl Street Torrance, CA 90510	Viable surface sampling shall be done at least monthly for ~~low and medium risk level~~ sterile-to-sterile compounding and weekly for ~~high risk~~ non-sterile to sterile compounding. Low, medium, and high-risk levels are not defined in the regulations. These terms must be defined to match the USP 797 criteria for each risk level. The criteria are included in 1751.8(a) through (c) but the terms "low and medium risk-level" and "high-risk" are not used.	Agreed: Language updated
1751.4(i)	Harbor Compounding Pharmacy Mai Tran and Sam Kitahara	We believe that weekly air sampling testing for high risk compounding would be overly cautious and extremely cost prohibitive for independent sterile compounding pharmacies. Current USP 797 guidelines only require volumetric air sampling for high risk compounding every 6 months. **Air Sampling Frequency and Process—**Air sampling shall be performed at least semiannually (i.e., every 6 months) as part of the re-certification of facilities and equipment. We recommend changing proposed language to: Volumetric air sampling by impaction shall be done at least once every 6 months for low, medium, and HIGH risk level compounding.	Agreed: Language updated
1751.4(i)	Community Regional Medical Center Bruce Lepley, Director of Pharmacy	**Reason for Concern:** The most recent USP 797 regulations state that viable surface sampling be done periodically. Many hospitals conduct surface sampling every six months to coincide with the requirements for PEC and cleanroom certification. Pharmacies may also not have access to qualified individuals every month for surface sampling, but would have access to these qualified individuals every six months for the PEC and cleanroom certifications. **Solution:** Reduce the viable surface sampling requirement to every six months.	Reject: Language changed from "monthly" to "quarterly"
1751.4(j)	California Pharmacist Association Brian Warren	The proposed regulations establish requirements for a "comfortable, well-lighted working environment," with specific standards for temperature and humidity. While maintaining a comfortable work environment for compounding personnel is advisable, it is unclear that such a requirement belongs in regulations. We recommend that the Board remove the requirements in subdivision (j) or rewrite them to be less specific, such as maintaining a comfortable work environment that is conducive to sterile compounding.	Reject: Keeping comfortable and well-lighted working environment; however, removed humidity level comment.
1751.4(j)	BJ Bartleson, RN, MS, NEA-BC California Hospital Association	Recommend deleting "which includes a room temperature of" since this applies to personal comfort and not directly to medication or consumer safety	Reject: USP 797 Facility Design and Environmental Contrals Guidelines
1751.4(j)	UCSD Research Pharmacy Leticia Muttera, Pharm. D	Is temp ≤ 20 degrees C for pharmacies with isolators as well? This temp goes below USP definition of controlled room temp. We typically keep the pharmacy at 20-25 degrees C. Similarly with isolators, does humidity need to be measured? Typically most pharmacies do not measure humidity.	Reject: USP 797 Facility Design and Environmental Contrals Guidelines
1751.4(j)	Sutter Health Jeannette Hanni	Current: "The pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20 degrees Celsius (68 degrees Fahrenheit) or cooler to maintain comfortable conditions for ompounding personnel when attired in the required....." Recommend deleting this statement "which includes a room temperature of..... since it applies to personal comfort and not to medication or consumer safety. Current: "Humidity levels should be consistent with ASHRAE Standard 55 (30-65% RH). Recommend adding the definition of humidity to the definitions page.	Reject: USP 797 Facility Design and Environmental Contrals Guidelines
1751.4(j)	GrayMatter Pharmacy Services, Inc Michael Moore, R.Ph.	Are you kidding me? What if I have poor circulation and I need a temperature of 72 or greater or I begin to shiver? Why would the board get into the business of determining what is right for everyone? What about sound levels? What about candle-lumen measurements for light? What about the angle staff might be required to bend over during the compounding process? My recommendation is that this language be stricken or use some useless language such as "every effort will be made to ensure that the work environment will be comfortable."	Reject: USP 797 Facility Design and Environmental Contrals Guidelines

Code Section	Commenter	Comment	Board Response
1751.4 (j)	Community Regional Medical Center Bruce Lepley, Director of Pharmacy	**Reason for Concern:** In the definitions section you describe a controlled room temperature (page 3) to be between 68 F to 77F and we agree that this is an appropriate range. We believe that maintaining a room temperature range of 68F to 77F in the areas where pharmacy personnel who are compounding in addition to the Room Humidity requirements stipulated in the proposed regulation is sufficient to mitigate risk of particle control in the compounding process. **Solution:** Include that a temperature range of 68F to 77F is appropriate for room temperature to maintain comfortable conditions for compounding personnel.	Reject: USP 797 Facility Design and Environmental Contrals Guidelines
1751.5(a)(6)	Sutter Health Jeannette Hanni	Recommend adding "severe" before rashes and deleting "sunburn". If a sunburn blisters and runs, it would be included in the category of "open sores".	Reject: "Severe" is not measurable and is subjective
1751.5(a)(6)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommend changing wording to: "Individuals with "exposed" rashes, sunburn…" Rationale: If the conditions are not exposed, a contamination problem is not realistic.	Reject: While it may be unlikely, contamination can still occur.
1751.5(a)(6)	California Society of Health-System Pharmacists Dawn Benton	Recommend changing wording to: "Individuals with "exposed" rashes, sunburn…" Rationale: If the conditions are not exposed, a contamination problem is not realistic.	Reject: While it may be unlikely, contamination can still occur.
1751.5(a)(6)	Providence Heath & Services Southern California Region 20555 Earl Street Torrance, CA 90511	*Individuals experiencing rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections, or those wearing cosmetics shall be excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.* *Providence recommends adding the specific ISO Classes of the restricted compounding areas to align with the USP 797 guidelines.*	Agreed: Language updated
1751.5(a)(6)	GrayMatter Pharmacy Services, Inc Michael Moore, R.Ph.	I believe this was brought up at the public comment last meeting, but if someone has a rash on an unexposed area are they still restricted? Is that considered a remedy?	Reject: While it may be unlikely, contamination can still occur.
1751.5(a)(6)	BJ Bartleson, RN, MS, NEA-BC California Hospital Association	Recommend in (a). (6) adding "Severe" to rashes and omitting "sunburn".	Reject: "Severe" is not measurable and is subjective
1751.5(2)(3)(5)	Charles A. Reynolds, Pharm.D., B.C.P.P UCLA Health System	Similar to 1751.4(g) clarification is needed on the gowning procedure in a non-ISO classified segregated compounding area such as a satellite. After donning shoe covers, head cover, and face mask, compounding personnel would need to walk away from the segregated compounding area to perform hand hygiene. However, the proposed language states that the personal protective equipment is donned immediately outside of the segregated compounding area. In a non-ISO classified area, it is not possible to gown in this manner. This procedure only makes sense in an ISO classified cleanroom environment where personal protective equipment is donned in the anteroom (ante-area). Separate hand hygiene and garbing procedures are needed for non-ISO classified rooms. Gloves to be disinfected by sterile isopropyl alcohol does not make sense in a non USP 797 cleanroom environment.	Reject: Still a sterile environment
1751.6(e)(1)(E)	McGuff Compounding Pharmacy Services, Inc William J. Blair, Pharm.D., MBA Vice President and Director of Pharmacy Services	Comment: Change to "the same amount or greater" to allow some flexibility	Agreed: Language updated
1751.6(i)	Charles A. Reynolds, Pharm.D., B.C.P.P UCLA Health System	This regulation mixes sterile to sterile compounding training with non-sterile to sterile compounding training. These need to be separated as not all staff will be performing both, and the requirement should fit the actual practice.	Reject: Training definition is broad, and must be documented by the PIC and pharmacy

Code Section	Commenter	Comment	Board Response
1751.7(a)	San Mateo Medical Center Gary L. Horne, Director of Pharmacy	In addition to the comments above, it should be noted that the language that reads "…end product shall be examined on a periodic sampling basis as determined by the pharmacist-in- charge to assure that it meets required specifications." does not state that laboratory qualitative and quantitative analysis be performed. Current guidelines such as the 2014 ASHP Guidelines on Compounding Sterile Preparations and USP Chapter <797> both state that end product sterility testing is not required for preparation of low and medium risk CSP, provided those CSP are assigned an appropriate BUD and stored accordingly. It is important that pharmacies understand that laboratory testing for sterility should not be required for sterile preparations compounded on a one-time basis for administration within seventy two {72} hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia- National Formulary {USP37-NF32) Through 2nd Supplement {37th Revision, Effective December 1, 2014}, hereby Incorporated by reference." If the CSP is compounded by the health care facility.	Reject: Quality Assurance Program
1751.7(a)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	Please consider deleting the word “written”. This will allow pharmacies to maintain electronic policy and procedures, which are more easily retrievable. There are many facilities that are using systems to electronically store and track policy and procedure archiving, renewals, revisions, and due dates.	Reject: "Written" does not mean a hard written document
1751.7(b)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	1. The volume transferred during the compounding process may vary in amount depending upon the final amount of sterile drug preparation produced. If the SBOP of pharmacy desires to mimic every variation in volume possible during the compounding process the number of media fill tests required would be infinite and not practical. Recommend revise the sentence as follows: The media fill testing process shall be as complicated as the most complex manipulations performed by staff~~. and contain the same amount of volume transferred during the compounding process~~.(i.e. insert a period after the word staff and delete the remainder of the sentence.	Reject: The PHY needs to be able to figure out the number of transfers
1751.7(b)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	2. With respect to the “personnel competency” that begins with the 6th sentence agree and support the requirement of media fill testing at least every 12 months for sterile to sterile compounding and at least every six months for individuals compounding sterile products from non-sterile ingredients. However; concerned that the language pertaining to unacceptable quality assurance program results, compounding process or equipment changes/replacements, and facility modifications is too broad and may not be warranted keeping in mind the Media Fill Test (MFT) is a method to determine the skill of personnel to aseptically prepare compounded sterile preparations. For example, when an individual staff member is observed to be using improper aseptic techniques, re-validation of the individuals’ MFT competency after being re-instructed to ensure correction of all aseptic work practice deficiencies is warranted but re-validation of the MFT competency of all personnel is not. Compounding Quality Assurance programs typically include many process or performance indicators; which may or may not be impacted by aseptic work practices, for example, process indicators related to medication storage temperature monitoring. If there were an unacceptable result with this process indicator that is included in the Quality Assurance Program, the language in this section would indicate process re-validation with a MFT would be required. Re-validation should be appropriate to the circumstance(s) and should be specific to the personnel found to be deficient.	Reject: Pharmacy must identify personnel competency requirements in Pharmacy P&P.
1751.7(b)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	Recommend the following changes: Personnel competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile products from non-sterile ingredients. Aseptic work practice assessments via media fill tests must be revalidated, as appropriate to the circumstance and or personnel found to be deficient, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile drug preparations are repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns or whenever improper aseptic techniques are observed.	Agreed: Language updated

Code Section	Commenter	Comment	Board Response
1751.7(b)	Central Admixture Pharmacy Services, Inc William Jones	Recommend removing the requirement to revalidate personnel when equipment used in the compounding process of sterile drug preparations are repaired or replaced. When compounding equipment such as an automated compounding device is repaired or a new component from the manufacturer has been sent as a replacement this does not change the process and should not require a new validation. It may be more appropriate to require a qualification of the equipment to make certain it is operating properly.	Removed "repaired"; however, "replaced" remains
1751.7(b)	McGuff Compounding Pharmacy Services, Inc William J. Blair, Pharm.D., MBA Vice President and Director of Pharmacy Services	Comment: Change to “the same amount or greater” to allow some flexibility	Agreed: Language updated
1751.7(c)	California Pharmacist Association Brian Warren	(c) All **sterile** compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, all compounding personnel must successfully complete a gloved fingertip sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations	Agreed: Language updated
1751.7(c)	Hartley Medical, William Stuart	a. Comment: I fail to see the significance and benefit of testing fingertips three times during the gowning and gloving process. This requirement represents that individuals compounding sterile preparations can aseptically don gloves prior to compounding sterile preparations. This requirement does not represent fingertip conditions while compounding sterile preparations under dynamic conditions. b. Recommendation: I recommend removing the requirement of testing fingertips three times during the gowning process, and consider fingertip assessment under dynamic conditions.	Reject: Testing is required
1751.7(c)	Charles A. Reynolds, Pharm.D., B.C.P.P UCLA Health System	Gloved fingertip sampling should only be required for personnel working in ISO-classified areas while wearing sterile gloves. Gloved fingertip sampling in non-ISO classified areas should not apply since there is exposure to non-ISO classified air.	Reject: Anyone working in a PEC needs to complete this part of the process validation
1751.7(e)	Marie Cottman: Hearing Testimony	Direct conflict with USP 797 guidelines for testing products. Batch definition USP 71 does not require pyrogen testing on non-injectable products, ie eye drops. Add faster forms of testing (RDI testing)	Reject: All non-sterile to sterile should be pyrogens tested. RDI scan system is not yet USP approved
1751.7(e)	Cedars-Sinai Katherine Palmer Rita Shane	Sterility and pyrogen testing will enable identification of potential patient risks.	Reject: No Recommendations
1751.7(e)	California Pharmacist Association Brian Warren	First, with respect to the non-sterile ingredients being compounded, only active ingredients should apply for testing. Second, while the standards proposed here closely mirror those in USP 37 <797>, one important exemption in the USP standards was excluded from the proposed regulations. USP 37 <797> establishes end-product testing requirements for high risk compounding. The USP requirements specifically state that “sterility tests for autoclaved CSPs are not required unless they are prepared in batches of more than 25 units.” We believe that this standard should carry over into California regulations. The Board states that the intent of the changes to Section 1751.7 is to “[address] the problem of ensuring that board regulations are aligned with compounding standards in USP 37 <797> and reducing such discrepancy for the compounding profession who are compounding drug products in California and shipping into California so as to ensure the safety of all consumers receiving compounded drugs in California.” In order to maintain alignment with USP 37 <797>, the sterility testing exception for batches of 25 of fewer should apply to California regulations as well.	Reject: However, language has been updated

Code Section	Commenter	Comment	Board Response
1751.7(e)	California Pharmacist Association Brian Warren	Third, we recommend deleting the proposed sentence "This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile." Per USP 37 <797>, in the absence of sterility and pyrogen testing, the Beyond Use Date assignment is restricted, depending upon the risk level of the sterile compounding (low, medium or high). For example, consider the compounding of alprostadil. A pharmacist will reconstitute the full 500mcg and use that as stock to compound the finished preparation. The pharmacist then performs end product testing of that stock for sterility and pyrogens. Under the above-mentioned requirement, even if the pharmacist compounds a medium risk product (sterile WFI and sterile alprostadil) and dilutes this to a 30mcg/ml, it would be mandated to perform additional end product testing. In our example, per USP 37 <797> sterility and pyrogen testing would only be required at the end-product stage for the pharmacist to assign a BUD of 90 days frozen (in the absence of such testing, the pharmacist would be limited to assigning a BUD of 45 days frozen). Deleting this section is consistent with USP 37 <797> because these proposed regulations adopt USP's beyond use dating requirements in Section 1751.8. Fourth, subdivision (e) provides specific instances and conditions for when a batch-produced sterile drug preparation may be dispensed prior to receipt of test results. The only conditions that such a drug may be dispensed are "where failure to dispense could result in loss of life, or intense suffering." There are other clinically justifiable reasons for releasing the drug quarantine, short of death or intense suffering. We recommend adding "clinically adverse outcome" to the instances in which a drug may be dispensed.	Reject: However, language has been updated
1751.7(e)(1)(C)	California Pharmacist Association Brian Warren	subdivision (e)(1)(C) requires written consent by the prescriber when a batch-produced sterile drug preparation is released from quarantine. Prescribers should be able to provide their consent to dispense over the phone, especially given that this only occurs during an emergency. We recommend striking the word "written."	Reject: We need to know the prescriber and not the agent was contacted
1751.7(e)(2)(A)	California Pharmacist Association Brian Warren	Delete "Daily observation of the incubating test specimens."	Reject: Daily is required
1751.7(e)(2)(B)	California Pharmacist Association Brian Warren	Limits dispensing of batch-produced sterile drug preparations prior to receiving test results only in such quantity necessary to meet the immediate need. We recommend modifying this to the amount that is "reasonably necessary," given that the exact amount may not be known at the time of the emergency. A pharmacist should not be penalized if a small number of doses are dispensed but they are not all used.	Reject: Current language is broad enough
1751.7(e)(2)(B)	Unknown Speaker at Hearing	Change the wording to pyrogen USP chapter 85 limits as the end point for toxins	Agreed: Language updated
1751.7(e)(2)(B)	Hartley Medical, William Stuart	a. Comment: A pyrogen is a lipopolysaccharide section of a bacterial cell wall. A pyrogen cannot biologically grow. I recommend changing the wording to state pyrogen concentration that exceeds USP monograph or USP Chapter <85> endotoxin limits.	Agreed: Language updated
1751.7(f)	Charles A. Reynolds, Pharm.D., B.C.P.P UCLA Health System	Again the wrong definition of 'batching' in 1735.1b (see previous) applies here. Incorrect application of the term will lead to interpretation problems. Needs to be clarified.	Reject: Section 1751.7(f) does not exist in regulation. However, language in 1735.1(b) has been changed.
1751.8	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommendation: Change language to support longer beyond use dating with the use of barrier isolators, provided that these primary engineering controls maintain ISO Class 5 air quality, and meet the requirements delineated in 1751.4(f). Rationale: The current regulatory language does not state that preparations compounded in barrier isolators that meet the requirements delineated in 1751.4(f) may be assigned the Beyond Use Dates as outlined in sections 1751.8 (a)(b)(c). The proposed language does not acknowledge that barrier isolators can provide ISO Class 5 air quality, even when located in a room that does not meet ISO Class 7 conditions. This could be an important strategy for preparing CSPs with beyond use dates exceeding 12 hours in medication satellites or in inpatient pharmacies that do not have a dedicated clean room.	Agreed: Language updated

Code Section	Commenter	Comment	Board Response
1751.8	California Pharmacist Association Brian Warren	In addition to the requirements and limitations of section 1735.2, subdivision (h), **and in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify a more extended beyond use date**, every sterile compounded drug preparation shall be given and labeled with a beyond use date that conforms to the following limitations, except that the beyond use date shall not exceed any expiration date or beyond use date provided by the manufacturer for any component in the preparation	Agreed: Language updated
1751.8	Hartley Medical, William Stuart	a. Comment: The proposed regulations are based primarily on USP chapter 797. It is my understanding that the USP Sterile Compounding Committee developed the beyond use guidelines based upon consensus and not derived from scientific studies or publications. One of the primary principles of the USP chapter 797 is: "They provide a foundation for the development and implementation of essential procedures for the safe preparation of low-risk, medium-risk, and high-risk level CSPs and immediate-use CSPs, which are classified according to the potential for microbial, chemical, and physical contamination." I have discussed this matter with many clinicians and USP Sterile Compounding Committee Members and their focus has always been on the probability of contamination. Probability does not equal certainty. Also stated in this chapter; "The use of technologies, techniques, materials and procedures other than those described in this chapter is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein". Our interpretation of this guideline supports alternative methods to produce sterile compounded preparations. In many sections of USP 797 references to USP 795 are noted as it relates to beyond use dating. Within chapter 795 it is stated, "In assigning a beyond use date for a compounded drug preparation, in addition to using all available stability information compounder is also to use his or her pharmaceutical education and experience." Additionally, within USP chapter 797 the section Responsibility of Compounding Personnel: item #10, BUD's are assigned on the basis of direct testing or extrapolation from reliable literature sources and other documentation. There are many concerns with the beyond use date guidelines as it relates to storage and temperature considerations. There are a certain number of compounded preparations that cannot be stored at temperatures below room temperature. More specifically, high concentration intraspinal solutions will precipitate at temperatures less than 21 Celsius (room temperature) and render these preparations unsuitable for administration.	Reject: No Recommendations for changes
1751.8	GrayMatter Pharmacy Services, Inc Michael Moore, R.Ph.	When I have discussed the difficulties associated with complying with the language in this section as it relates to a small hospital pharmacy with limited space we were told that if we purchased a CAI we would be able to get BUD greater than 12 hours currently afforded to us by the proposed regulation. However, when I read the various "options" for compounding areas it does not appear that we would get BUD greater than 12 hours even if we begin utilizing a CAI. 1751.8(a) describes a PEC in an ISO 7 buffer area, (b) describes the same environment, (c) describes non-sterile to sterile, and (d) describes our current situation. If the language were changed to say "ISO class 5 PEC WITH an ISA 7 buffer area" then I think we would be in compliance. In most CAIs the buffer area is adjacent to the class 5 area of the hood. The class 5 area is not wholly contained in a class 7 area.	Agreed: Language updated

Code Section	Commenter	Comment	Board Response
1751.8	Hartley Medical, William Stuart	Continuation: b. Past Studies on Contamination: There have been many studies addressing the contamination rate of compounded sterile preparations over the past four decades. Many the studies are focused on hospital-based pharmacy settings versus non-hospital based compounding pharmacies. In my review of the studies I found that critical information was omitted. This includes sterile compounding environment, staff gowning, environmental conditions, hand washing and gloving , and sterile gloves versus non-sterile gloves to name a few. I present the following publication; AJHP Vol 62, November 15th, 2005; I.V. Admixture Contamination Rates: Traditional Practice Site Versus a Class 1000 Clean Room. The purpose of this study was to show the contamination rates associated with medium risk CSP's in a traditional practice versus those in a class 1000 clean room. I wish to highlight two important issues. First, this publication stated that the class 1000 clean room received HEPA filtered air and the room air changes per hour (ACPH) were 39.6. This is just over the USP 797 standard. Second, they performed a viable (bacteria) air sampling. Their average number of CFU's per cubic meter was 13. This number of CFU's exceeds USP 797 guidelines. This room was poorly designed in the air changes per hour which were inadequate to properly remove viable and nonviable particulates. I have yet to find a study evaluating the contamination rates of CSP's within an ISO 4 PEC device in an ISO 6 clean room with active viable and non-viable environmental monitoring. c. Recommendation: Consider adding text such as; " For sterile compounded preparations, in the absence of direct sterility testing results or appropriate information sources that justify different limits…". One could also consider incorporating language for process validation to extend beyond use dates.	Reject: No studies provided to support recommendation
1751.8(a)	California Pharmacist Association Brian Warren	***A beyond use date of no more than 48 hours at controlled room temperature; 14 days at controlled cold temperature; and 45 days at controlled freezer temperature shall be given to a*** ~~**Where the**~~ sterile compounded drug preparation that was compounded solely with aseptic manipulations **when all of the following apply**:	Agreed: Language updated
1751.8(a)(1)	California Pharmacist Association Brian Warren	**The preparation was compounded** entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area with an ante-area, using only sterile ingredients, products, components, and devices.; ~~**and**~~	Agreed: Language updated
1751.8(a)(2)	California Pharmacist Association Brian Warren	The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entires into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation.~~**; and**~~	Agreed: Language updated
1751.8(a)(3)	California Pharmacist Association Brian Warren	Compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing ~~**in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed the following: 48 hours at controlled room temperature; 14 days at controlled cold temperature; and 45 days at controlled freezer temperature**~~	Agreed: The language has been updated. Time table left in regulations.
1751.8 (a)-(e)	UCSD Research Pharmacy Leticia Muttera, Pharm. D	Or compounding aseptic containment isolator?	Reject: Unsure of what recommendation is
1751.8(a)(2)	GrayMatter Pharmacy Services, Inc Michael Moore, R.Ph.	Need to define "mixing manipulations"	Reject: Definition not required

Code Section	Commenter	Comment	Board Response
1751.8 (a) and (b) and (c)	Community Regional Medical Center Bruce Lepley, Director of Pharmacy	**Reason for Concern:** Compounding aseptic (containment) isolators (CACIs) are discussed in section 1751.4 (f) (1-3) in terms of use outside of an ISO Class 7 buffer area and this beyond use dating section is unclear about the CACIs BUD. The intention of both sections appears that CACIs meeting the criteria in 1751.4 (f) (1-3) may utilize the BUD for compounding in 1751.8 (a-c) and if the CACI does not meet the criteria, the preparations are limited to 12 hour BUD or less. **Solution:** Add language to 1751.8 (a) (1), (b) (1) and (c) "…with an ante-area or within a compounding aseptic (containment) isolator meeting the criteria of section 1751.4 (f) (1-3)."	Agreed: Language updated
1751.8(a),(b),and (c)	Providence Heath & Services Southern California Region	Where the sterile compounded drug preparation was compounded solely with aseptic manipulations (1) entirely within an ISO Class 5 PEC ~~located in an ISO Class 7 buffer area with an ante-area,~~ or better air quality. Proposed language restricts sterile compounding with USP 797 defined beyond use dating to only within an ISO 7 cleanroom with an ante-area. USP 797 guidelines allow for sterile compounding within a CAI or CACI that meets all of the operational criteria as defined in Section 1751.4(f) and use of beyond use dating specified. USP 797 high-risk level sterile compounding that aligns with proposed Section 1751.8(c) does not require use of an ISO Class 5 PEC, ISO Class 7 buffer area or ante-area. The language contradicts the last paragraph of the same section 1751.8(c) *For the purposes of this paragraph, "non-sterile" includes sterile contents of commercially manufactured preparations, sterile surfaces of devices, and containers for the preparation, transfer, sterilization, and packaging of compounded sterile preparations, that are exposed to worse than ISO Class 5 air quality for more than one hour.*	Agreed: Language updated
1751.8(a)(3)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	Insert the words "before administration is initiated" after the word "following" to ensure that board regulations are more closely aligned with compounding standards in USP 37 <797> and the beyond use date definition being proposed in CCR 1735.1 (c).	Reject: Defined in BUD definition in 1735.1
1751.8(a)(3), (b)(3),and(c)	Providence Heath & Services Southern California Region	...in accordance with standards for sterility testing found in Chapter ~~797~~ 71of the United States Pharmacopeia - National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014. USP 797 references USP 71 *Sterility Tests.* Providence recommends referencing USP Chapter 71 directly.	Reject: Using USP 797
1751.8(b)	Providence Heath & Services Southern California Region	(1) entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area with an ante area, using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and/or (2) the compounding process involves complex aseptic manipulations other than the single-volume transfer; and/or (3) the compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing. Providence recommends aligning with *Medium - Risk Level CSPs* conditions which include "one or more" of the listed criteria.	Agreed: Language updated
1751.8(b)	California Pharmacist Association Brian Warren	**A beyond use date of no more than 30 hours at controlled room temperature; 9 days at controlled cold temperature; and 45 days at controlled freezer temperature shall be given to a ~~Where the~~** sterile compounded drug preparation **that** was compounded solely with aseptic manipulations **when all of the following apply**:	Agreed: Language updated

Code Section	Commenter	Comment	Board Response
1751.8(b)(1)	California Pharmacist Association Brian Warren	**The preparation was compounded** entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area with an ante-area, using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions.; ~~**and**~~	Agreed: Language updated
1751.8(b)(2)	California Pharmacist Association Brian Warren	the compounding process involves complex aseptic manipulations other than the single- volume transfer.; ~~**and**~~	Agreed: Language updated
1751.8(b)(3)	California Pharmacist Association Brian Warren	the compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing ~~**in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed the following: 30 hours at controlled room temperature; 9 days at controlled cold temperature; and 45 days at controlled freezer temperature**~~.	Agreed: The language has been updated. Time table left in regulations.
1751.8(b)(3)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	Insert the words “before administration is initiated” after the word “following” to ensure that board regulations are more closely aligned with compounding standards in USP 37 <797> and the beyond use date definition being proposed in CCR 1735.1 (c).	Reject: Defined in BUD definition in 1735.1
1751.8(b)(3)	GrayMatter Pharmacy Services, Inc Michael Moore, R.Ph.	Like what? I’m going to need examples. Or the state is going to have to come up with a defined time: ex. “if it takes more than 30 seconds to dissolve the powder”	Reject: Using language from USP 797
1751.8(c)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	1. Insert the words “before administration is initiated” after the word “following” to ensure that board regulations are more closely aligned with compounding standards in USP 37 <797> and the beyond use date definition being proposed in CCR 1735.1 (c). 2. The text “or where the sterile compounded drug preparation lacks effective antimicrobial preservatives” is taken out of context relative to USP 797 applicability when compounding sterile products outside of an ISO Class 5 environment. If adopted as proposed, the beyond use dating requirements described in this regulation would be applied when a sterile preparation that contains a non-preserved ingredient is compounded within an ISO class 5 PEC located in an ISO Class 7 buffer area with an ante-area. This would unnecessarily impose the more conservative beyond use date requirements normally assigned to “high risk” compounding resulting in increase expense and waste of drug resources as a result of the shorted “shelf life”.	Language has been updated
1751.8(c)(1)	California Pharmacist Association Brian Warren	**A beyond use date of no more than 24 hours at controlled room temperature; 3 days at controlled cold temperature; and 45 days at controlled freezer temperature shall be given to a** ~~**Where the**~~ sterile compounded drug preparation **that** was compounded solely with aseptic manipulations entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area with an ante-area, using non-sterile ingredients, including manufactured preparations not intended for sterile routes of administration, or non-sterile devices, before terminal sterilization, or where the sterile compounded drug preparation lacks effective antimicrobial preservatives, ~~**in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed the following: 24 hours at controlled room temperature; 3 days at controlled cold temperature; and 45 days at controlled freezer temperature**~~.	Agreed: Language updated
1751.8(c)(2)	California Pharmacist Association Brian Warren	For the purposes of this **subdivision** ~~**paragraph**~~, “non-sterile” includes sterile contents of commercially manufactured preparations, sterile surfaces of devices, and containers for the preparation, transfer, sterilization, and packaging of compounded sterile preparations, that are exposed to worse than ISO Class 5 air quality for more than one hour.	Agreed: Language updated

Code Section	Commenter	Comment	Board Response
1751.8(d)	California Pharmacist Association Brian Warren	**A beyond use date shall specify that storage and exposure periods cannot exceed 12 hours in a laminar air flow workbench or biological safety cabinet when ~~Where~~** the sterile compounded drug preparation was compounded solely with aseptic manipulations **and all of the following apply:**	Agreed: Language updated
1751.8(d)(1)	California Pharmacist Association Brian Warren	**The preparation was compounded** entirely within an ISO Class 5 PEC that is located in a segregated compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed**.~~; and~~**	Agreed: Language updated
1751.8(d)(1)	Providence Heath & Services Southern California Region	*(1) entirely within an ISO Class 5 PEC that is a compounding aseptic isolator (CAI} or a compounding aseptic containment isolator (CACI) that does not meet the requirements described in Section 1751.4(/) or is a laminar airflow workbench (LAFW) or a biological safety cabinet (BSC) that is located in a segregated compounding area and restricted to sterile compounding activities,...* *Proposed language in this section does not fully align with the UPS 797 guidelines for Low-Risk Level CSPs with 12-Hour of Less BUD. Recommend specifying the criteria for IS05 PECs that fall under this category. USP 797 guidelines allow for sterile compounding within a CAI or CACI that meets all of the operational criteria as defined in Section 1751.4(f) and use of beyond use dating specified in Sections 1751.8(a) and (b) corresponding to beyond use dating of Low-Risk Level CSPs and Medium-Risk Level CSPs.*	Agreed: Language updated
1751.8(d)(1)	Community Regional Medical Center Bruce Lepley, Director of Pharmacy	**Reason for Concern:** The most recent USP 797 regulations state that viable surface sampling be done periodically. Many hospitals conduct surface sampling every six months to coincide with the requirements for PEC and cleanroom certification. Pharmacies may also not have access to qualified individuals every month for surface sampling, but would have access to these qualified individuals every six months for the PEC and cleanroom certifications. **Solution:** Reduce the viable surface sampling requirement to every six months.	Reject: Language changed to quarterly
1751.8(d), (d)(1), (d)(3)	Douglas Barcon, Pharm.D., Barcon & Associates	Section (d)(1) specifies a segregated compounding area and (d)(3) specifies that the BUD cannot exceed 12 hours in the absence of passing a sterility test in a laminar air flow workbench or biological safety cabinet. This is addressed in USP 797. Section (d) addresses sterile compounding in a segregated compounding area with compounding manipulations in an ISO Class 5 PEC. It makes no reference to use of an ISO Class 5 compounding aseptic isolator or compounding aseptic containment isolator that is compliant with ISO Class 5 as specified in 1751.4 (f)(1), (f)(2), and (f)(3), and certified by the manufacturer as specified in 1751.4 (h) in a non-ISO rated room, which could include a segregated compounding area. Placement of a compliant and manufacturer certified CAI or CACI in any room, would permit the full USP 797 beyond use dates. Perhaps there should be a paragraph (4) added to 1751.8 (d) or a new lettered section should be added to address use of a CAI or CACI in a segregated compounding area or other closed room. A change such as this would address and eliminate the BUD issue in critical access hospitals where a pharmacist is not available to compound 24 hours per day. In the case of a trained and properly garbed non-pharmacist or non-pharmacy technician doing such compounding, such as a nurse, the preparations shall be limited to low-risk and the BUD should not exceed 24 hours when refrigerated. When I had an email dialog with Eric Kastango in late July, he too agreed that this would be an acceptable solution for critical access hospitals, and that it would be up to the state to draft such a regulation for critical access hospitals. If a new lettered section is added, the current (f) specifies (a) through (e), which would also need to be changed.	Agreed: Language updated
1751.8(d)(2)	California Pharmacist Association Brian Warren	the compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer's original containers**.~~; and~~**	Reject: should be and

Code Section	Commenter	Comment	Board Response
1751.8(d)(3)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommendation: "….the beyond use date shall specify that administration shall commence no longer than 12 hours after preparation. Rationale: It appears as though this language is attempting to describe the requirements of "Low-Risk Level CSPs with 12-Hour or Less BUD" in USP Chapter 797. The proposed language appears to require that the compounded drug preparation must be stored in a laminar air flow workbench or biological safety cabinet. This is incorrect.	Agreed: Language updated
1751.8(d)(3)	California Pharmacist Association Brian Warren	the compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device**. ~~in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed 12 hours in a laminar air flow workbench or biological safety cabinet~~**	Agreed: Language updated
1751.8(d)(3)	California Society of Health-System Pharmacists Dawn Benton	Recommend changing language: ", the beyond use date shall specify "that administration shall begin no later than 12 hours after preparation". Rationale: The proposed language is confusing and ambiguous and not consistent with industry standards and appears to say that after preparation, a compounded drug must be stored in a laminar airflow workbench or biological safety cabinet.	Agreed: Language updated
1751.8(d)(3)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	Recommend inserting the words "before administration is initiated" after the word "periods" to ensure that board regulations are more closely aligned with compounding standards in USP 37 <797> and the beyond use date definition being proposed in CCR 1735.1 (c). Recommend ending the sentence after the word "hours". The location of compounding is already specified in 1751.8(d)(1) and as proposed, the way it reads it is as if the preparation is being stored or exposed in the actual PEC; which I don't believe was intended.	Agreed: Language updated
1751.8(d)(3)	GrayMatter Pharmacy Services, Inc Michael Moore, R.Ph.	This would prevent our facility from even making "banana bags" for the staff. In a facility that is not 24 hours we will be depending on nursing to do more and more compounding of complicated products with multiple additives out on the floor. I fail to see how this would be in the best interest of public safety. It appears you are creating safety in one area at the expense of safety in another.	Reject: Unsure how sterility assurance would impact safety
1751.8(d)-(f)	Charles A. Reynolds, Pharm.D., B.C.P.P UCLA Health System	The BUD for nonhazardous products made within an ISO Class 5 PEC in a non-ISO classified room is 12 hours. The BUD for compounding a low volume (defined as 5 or less per week) of hazardous drugs is 12 hours. What is the BUD for compounding a higher volume of hazardous drugs if made in an ISO Class 5 laminar airflow hood in a non-ISO classified room – can it be set by the pharmacy?	Reject: 797 would still suggest a 12hr BUD but 800 needs to be consulted by HSP.
1751.8(e)	California Pharmacist Association Brian Warren	**A beyond use date shall specify that storage and exposure periods cannot exceed 12 hours when ~~Where~~** the sterile compounded drug preparation was compounded **under both of the following conditions:**	Agreed: Language updated
1751.8(e)	BJ Bartleson, RN, MS, NEA-BC California Hospital Association	Low volume is not defined in any current national guidelines. Recommend deleting the low volume definition since (1) Moderate and high volume would no longer be addressed in the regulations, 2) There is no existing official definition of low volume chemo preparation and (3) new guidelines are pending from USP. delete	Reject: Definition of Hazardous added

Code Section	Commenter	Comment	Board Response
1751.8(e)	Douglas Barcon, Pharm.D., Barcon & Associates	This section does not specify the ISO class of the room for compounding hazardous drugs. This section addresses both low-volume and non-low-volume hazardous drug compounding, but does not fully differentiate between the two. It only addresses a non-negative pressure room, which could be an ISO rated room or a non-ISO rated room. The beyond use date for a hazardous drug could be longer than 12 hours depending on the room and the PEC. There should be a separation between a biological safety cabinet and a compounding aseptic containment isolator in this section because they are functionally different. If a compounding aseptic containment isolator is used for hazardous drugs and it has been tested to be compliant with ISO Class 5 as specified in 1751.4 (f)(1), (f)(2), and (f)(3), and certified by the manufacturer as specified in 1751.4 (h) for use in a non-ISO rated room, the beyond use date should be as specified per USP 797 and USP 800 for the respective risk level at any volume. If the compounding aseptic containment isolator for hazardous drug compounding is compliant with ISO Class 5, but is not certified by the manufacturer for use in a room with air quality worse than ISO Class 7, then the beyond use date cannot exceed 12 hours. Ideally, the CACI should be vented to the outside and venting to the outside will be required by USP 800. If the PEC is an ISO Class 5 biological safety cabinet located in a worse than ISO Class 7 room that is negative pressure or non-negative pressure, the BUD for such preparations should not exceed 12 hours as specified. Ideally, the BSC should be vented to the outside and venting to the outside will be required by USP 800. Note that USP 800 intends to eliminate the non-negative pressure room clause for hazardous drug compounding, regardless of whether the PEC is certified by the manufacturer to be compliant for hazardous drug compounding in a non-negative pressure room. USP 800 also intends to eliminate the low-volume exemption for hazardous drug compounding.	Agreed: Language updated
1751.8(e)(1)	California Pharmacist Association Brian Warren	Using or containing hazardous drugs or components~~; and~~	Reject: Needs to be "and"
1751.8(e)(2)	Sutter Health Jeannette Hanni	Current "in facilities that prepare a low volume of hazardous drugs, where low volume is defined as five or less per week, the use of two tiers of containment (eg closed system transfer device within a biological safety cabinet or compounding aseptic containment isolator that is located in a non-negative pressure room) Recommend deleting the low volume definition since: 1) Moderate and high volume would no longer be addressed in the regulations AND 2) There is no existing official definition of low volume chemo preparation. AND 3) New guidelines are pending from USP.	Low Volume definition removed; however, reference remains pending USP 800 regulation

Code Section	Commenter	Comment	Board Response
1751.8(e)(2)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommendation: "using two tiers of containment (e.g., a closed system transfer device within a compounding aseptic isolator that meets the requirements delineated in 1751.4(f) that is located in a non-negative pressure room).may be assigned beyond use dates as specified in 1751.8 (a)(b)(c)." Rationale #1: Hazardous drugs prepared in a compounding aseptic containment isolator that meets the requirements delineated in 1751.4(f) may be assigned the Beyond Use Dates delineated in 1751.8 (a)(b)(c) Recommendation: We propose this definition for low volume: "A low volume is defined as less than or equal to a mean number of twenty doses per week, averaged over a period of one month." This would enable a hospital to treat a small number of patients requiring chemotherapy. Rationale #2: Patients who receive chemotherapy treatment in a hospital frequently receive multi-drug chemotherapy regimens. With the current definition of five or less preparations per week, it is unlikely that even one patient could be treated.	Low Volume definition removed; however, reference remains pending USP 800 regulation
1751.8(e)(2)	California Society of Health-System Pharmacists Dawn Benton	Recommend deleting the low volume definition. Rationale: Moderate and high volume would no longer be addressed in the regulations, 2) There is no existing official definition of low volume chemo preparation and (3) new guidelines are pending from USP.	Low Volume definition removed; however, reference remains pending USP 800 regulation
1751.8(e)(2)	California Pharmacist Association Brian Warren	In facilities that prepare a low volume of hazardous drugs, where low volume is defined as five or less per a week, the use of two tiers of containment (e.g., closed system transfer device within a biological safety cabinet or compounding aseptic containment isolator that is located in a non-negative pressure room)**~~. the beyond use date shall specify that storage and exposure periods cannot exceed 12 hours.~~**	Low Volume definition removed; however, reference remains pending USP 800 regulation
1751.8(e)(2)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	Recommend inserting the words "before administration is initiated" after the word "periods" to ensure that board regulations are more closely aligned with compounding standards in USP 37 <797> and the beyond use date definition being proposed in CCR 1735.1 (c).	Reject: Defined in BUD definition in 1735.1
1751.8(e)(2)	Community Regional Medical Center Bruce Lepley, Director of Pharmacy	**Reason for Concern:** The sentence is unclear how the preparation of low volume relates to the two tiers of containment (e.g. low volume and without two tiers of containment or low volume and with two tiers of containment). USP 797 does not have a section specific to this proposed language, nor does USP 800, limiting the beyond use date for hazardous drugs in a low volume facility to 12 hours or less. This may actually pose more of a risk for low volume facilities that must compound their hazardous drugs every 12 hours since they may not have the staff or resources to accomplish this frequency. **Solution:** Remove section (e) completely.	Low Volume definition removed; however, reference remains pending USP 800 regulation
751.8(e)(2)Page 3	Providence Heath & Services Southern California Region	Eliminate "low volume" in reference to the preparation of hazardous drugs. Each Providence pharmacy prepares, at a minim urn, an average of 25 doses per week for our most vulnerable patients. USP 797 guidelines do not define "low *volume,"* and we are uncertain how the board came to define "five or less per *week"* as a sufficient dosage. Hospital pharmacies should continue to compound sterile drug and hazardous drug preparations under specified conditions in the proposed regulations, without compromising patient health and safety.	Low Volume definition removed; however, reference remains pending USP 800 regulation

Code Section	Commenter	Comment	Board Response
1751.8(e),page34	Providence Heath & Services Southern California Region	Providence recommends removing 1751.8(e) and adding to section 1751.4(g): *Where the sterile compounded drug preparation was compounded (1) using or containing hazardous drugs or components; and* (2) in facilities that prepare a low volume of hazardous drugs, ~~where low volume is defined as five or less per a week~~, the use of two tiers of containment (e.g. closed system transfer device within a biological safety cabinet or compounding aseptic containment isolator that is located in a non-negative pressure room) the beyond use date shall specify that storage and exposure periods cannot exceed ~~12 hours~~ *those specified in accordance with the criteria listed in Sections 1751.8(a) through (c)*. Per USP 797, use of a closed system transfer device within a biological safety cabinet or CACI does not affect the determination of beyond-use dating. Negative or positive pressure of the room does not affect the determination of beyond-use dating; it only specifies the exposure risk of hazardous drugs to the environment The ISO Class air quality of the compounding conditions, compounding process and sterility of components determines the beyond-use dating. For example, compounding a sterile hazardous drug preparation in a negative pressure room that meets or exceeds IS07 buffer area quality within an ISOS PEC would be afforded a beyond-use date consistent with Low-Risk Level CSPs.	Low Volume definition removed; however, reference remains pending USP 800 regulation. BUD information defined in 1735.1.
1751.8(f)	GrayMatter Pharmacy Services, Inc Michael Moore, R.Ph.	This labeling requirement will be almost impossible to monitor and enforce. Asking nursing to add an additional label to the products that they compound will be exceedingly difficult.	Reject: This is about Patients not receiving expired drugs and drugs need to be labeled no matter who compounding them.
1751.8(f)	UCSD Research Pharmacy Leticia Muttera, Pharm. D	What about vaccines and IM antibiotics such as Rocephin 250mg IM x1 given in areas such as MD offices?	Reject: This only applies to Pharmacy Sterile Compounding
1751.8(f)	BJ Bartleson, RN, MS, NEA-BC California Hospital Association	delete	Reject: This is about Patients not receiving expired drugs and drugs need to be labeled no matter who compounding them.
1751.8(f)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	If a facility were to compound a sterile hazardous preparation under conditions that meet all of the requirements of subdivisions (a) through (e) except (e)(2) where the volume of hazardous drugs prepared exceeds five or less be a week, I would interpret this to mean immediate use requirements in this subdivision (1751.8(f)) apply. If this is a correct interpretation, then I have grave concerns about this subdivision with respect to compounding of sterile hazardous preparations. If the only requirement of subdivisions (a) through (e) that cannot be met is the volume requirement it would unnecessarily impose immediate use requirements such as "complete administration is witnessed by the preparer" and "beginning of administration commencing within one hours following the start of the compounding process". Hazardous drug compounding typically involves redundant safety checks during the preparation process and depending on the type of preparation may require an hour or more for proper medication activation (e.g. use of microspheres for chemo-embolization). The commencement of the administration of compounded hazardous preparations is highly reliant upon other patient care factors such as pump set up and priming, patient education, the administration of pre-medications and possibly other competing priorities the nurse or caregiver administering the medication is balancing. The one-hour interval between commencing of compounding and administration would be challenging, possibly unsafe, costly and would not be warranted in situations where the only requirement of the subdivision unmet is the volume of hazardous drug preparation. In addition, in this specific circumstance, having the preparer, commonly a Pharmacy Technician or in some cases a Pharmacist witness the administration does not reasonably offer a benefit to patient care it would only add costly labor resources especially with the hazardous drugs continuously infused over a 24 hour period.	Reject: (f) is addressing Immediate use only.. Chemotherapy is not a stat and should not be Immediate use and if it's a true STAT the administration needs to stat with in 1 hr.

Code Section	Commenter	Comment	Board Response
1751.8(f)	Kaweah Delta Medical Center Rheta Sandoval, Pharm.D.	To remedy this concern, language proposed in section 1751.8(f) could be modified from "for any of subdivisions (a) through (e)" to "for any of subdivisions (a) through (d). Alternatively, consider adding a section that would cover facilities that are compounding hazardous drug preparations in an ISO Class 5 PEC within a ISO Class 7 buffer area using two tiers of containment within a biological safety cabinet or compounding aseptic containment isolator (located in a non-negative pressure room) BUT are compounding volumes in excess of five per week.	Low Volume definition removed; however, reference remains pending USP 800 regulation
1751.8(f)	California Pharmacist Association Brian Warren	**(1)** Where any sterile compounded drug preparation was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (e), the sterile compounded drug preparation shall be labeled " for immediate use only" and administration shall begin no later than one hour following the start of the compounding process. Unless the " immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. This provision does not preclude the use of a PEC to compound an " immediate use" preparation. **(2)** Such "immediate use" preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.	Agreed: Language updated
1751.9	Unknown Speaker at Hearing	Reconsider limits of use of single use vials and multiple use vial and end dates.	Reject: No recommendations
1751.9	Hartley Medical, William Stuart	a. Comments: I have had many concerns regarding time limitations associated with single dose or multi-dose vials as they relate directly to sterile compounding of preparations. Numerous studies have been conducted regarding contamination rates of single-dose or multi-dose vials within healthcare institutions. In these studies, which were performed in hospital settings, the vials in use were on hospital floors. These studies were very useful in understanding contamination rates of vials utilized on the hospital ward. However, this environment is extremely different than that of an ISO 5 environment or better. I have been unable to locate any published studies of single-dose or multi-dose vial contamination rates within ISO 5 environment. The sterile preparation area for which the primary engineering control devices are located are designed to provide a more optimal environment for sterile compounding. Lastly, I spent over six years studying potential contamination of multi-dose vials utilized in an ISO Class 5 LAFW within my institution. We obtained samples from multiple use vials (approximately 50% utilized) and inoculated two types of growth medium and incubated for 14 days. Next, we removed the same vials (approximately 10% remaining fluid) from which the original samples were derived, and we aseptically fill each vial with growth media and incubated for another 14 days. As of this date we have yet to observe microbial growth. b. Recommendation: Please reconsider removing beyond use dates for single dose and multi-dose vials utilized in sterile compounding.	Reject: Time limits not extended

Code Section	Commenter	Comment	Board Response
751.9(a), (b), and (	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommendation: Include above language from USP 797 allowing the use of proven technologies with quality assurance procedures (for example, Closed System Transfer Devices) allowing for extension of BUD for single-dose vials. Rationale: One of the hallmarks of USP and Current Good Manufacturing Practices (cGMP) is the ability of entities under the guidelines to be innovative and advance practice with validated processes that differ from the current standards. The advancement of knowledge, technology, and validation processes in a very fluid environment must be allowed to flourish; thus the ability to design programs that meet or exceed current outcomes is essential. The key statement allowing this within the USP 797 is as follows: "The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein"	Reject: No reliable Data to Support the extension of BUD through use of CSTD
1751.9(a)	BJ Bartleson, RN, MS, NEA-BC California Hospital Association	delete	Reject: No Explanation Provided
1751.9(b)	BJ Bartleson, RN, MS, NEA-BC California Hospital Association	delete	Reject: No Explanation Provided
1751.9(b)	Cedars-Sinai Katherine Palmer Rita Shane	Cancer drugs have been associated with multiple drug shortages and adverse patient outcomes. One research study determined that substitution with cyclophosphamide for mechlorethamine resulted in significantly less efficacy in treatment of children with Hodgkin's lymphoma. Additionally, as a result, counterfeit chemotherapy is an area of national concern,until such time as E-Pedigree is available. Closed system transfer devices (CTSD) protect the vial from entry of external bacteria after initial puncture beyond the USP 797 approved 6 hour time limit. It has been shown that one of these systems maintains sterility of the vials to which it is attached for up to 168 hours (7 days). Recommendation: Allow use of CTSDs with supporting literature to extend the beyond use date of single dose vials of chemotherapy to 24 hours or use through the end of the shift whichever is shorter. This recommendation is more conservative than the timeframe of 7 days listed in the CTSD study and would assist institutions in conserving scarce chemotherapy medications.	Reject: No reliable Data to Support the extension of BUD through use of CSTD
1752	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommend deletion of 1752 entirely. Rationale: 1) Beyond the authority of the Board of Pharmacy to dictate the type of personnel that may deliver medication. 2) It should be left to the professional judgment of a pharmacist to determine the delivery methodology based on the patient's need in each individual situation.	Reject: This allows Pharmacist to carry and furish, which is with the Board of Pharmacy scope.
1752	California Society of Health-System Pharmacists Dawn Benton	Recommend deletion of 1752 entirely. Rationale: 1) Beyond the authority of the Board of Pharmacy to dictate the type of personnel that may deliver medication. 2) It should be left to the professional judgment of a pharmacist to determine the delivery methodology based on the patient's need in each individual situation.	Reject: This allows Pharmacist to carry and furish, which is with the Board of Pharmacy scope.
1753(b)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	For "(b)" Recommend deleting renumbering of 1751.1.1 from this regulatory proposal and considering updating those provisions in a future regulation revisions proposal. Rationale: This is an outdated drug list.	Reject: Outside Scope of Regulation

Code Section	Commenter	Comment	Board Response
1753(b)	California Society of Health-System Pharmacists Dawn Benton	Recommend deleting renumbering of 1751.1.1 from this regulatory proposal and considering updating those provisions in future revisions proposal. Rationale: This is an outdated drug list.	Reject: Outside Scope of Regulation
1753(b)	BJ Bartleson, RN, MS, NEA-BC California Hospital Association	Recommend review and revision of medication listed in this section	Reject: Outside Scope of Regulation
1753(c)	California Society of Health-System Pharmacists Dawn Benton	Recommend modifying language to “Have a specific treatment protocol “or order” from a prescriber for the administration of each medication contained in the portable container.” Rationale: A prescriber should be able to order a drug that is in the portable container for a use that is different than specified in the facility’s protocol for that drug.	Reject: Outside Scope of Regulation
1753(c)(1)(C)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommend modifying language to “Have a specific treatment protocol “or order” from a prescriber for the administration of each medication contained in the portable container.” Rationale: A prescriber should be able to order a drug that is in the portable container for a use that is different than specified in the facility’s protocol for that drug.	Reject: Outside Scope of Regulation
1753(e)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommend this section be reviewed based on current practice (use of electronic health records). Rationale: This section does not consider current practice such as the use of electronic health records and drug classifications. This section appears to be beyond the authority of the Board to dictate procedures in home health agencies and hospices.	Reject: Outside Scope of Regulation
1753(e)	California Society of Health-System Pharmacists Dawn Benton	Recommend this section be reviewed based on current practice (use of electronic health records). Rationale: This section does not consider current practice such as the use of electronic health records and drug classifications. This section appears to be beyond the authority of the Board to dictate procedures in home health agencies and hospices.	Reject: Outside Scope of Regulation
1754	California Society of Health-System Pharmacists Dawn Benton	Recommendation, if 1751.11 is updated by this regulation change proposal, then the reference numbering in 1754 (a) and (b) should be revised.	Reject: Outside Scope of Regulation
General Comment (No Code Section)			
	GrayMatter Pharmacy Services, Inc Michael Moore, R.Ph.	Please consider that much of what has been proposed is valuable, but it is an unreasonable expectation of all pharmacies to comply with every rule proposed. I strongly believe that these regulations will push the burden of compounding to the nursing staff. This is neither safe nor efficient. If the goal of the State Board of Pharmacy is to “protect the public” then I would argue that some of the language within these new regs will result in unintended consequences. I hope that the state board will step forward and accept some of the responsibility when an error is committed by nurses that are forced to compound medications for patients.	Reject: While the pending regulations are lengthily, the regulations are being put in place to increase patient safety in California It is the responsibility of the PIC of it location to keep the location in compliance.

Code Section	Commenter	Comment	Board Response
	Charles A. Reynolds, Pharm.D., B.C.P.P UCLA Health System	We would like to point out that bedside sterile administration by nursing (while not regulated by the Board) was decided years ago by both Centers for Medicare & Medical Services and The Joint Commission to be an unacceptable practice except in the treatment of true acute emergencies. We would also point out that the literature documents the safety of the practice of compounding within a certified ISO Class 5 biological hood (vertical or horizontal flow) as well as the decreased risk to the patient of such compounding in relation to bedside compounding. As such it appears to us that the current proposed regulations treat all compounding areas as under the same rules [i.e. USP 797 (and future versions) compliance] and will therefore force all compounding into a central area which will not be able to address the immediate needs of the hospitalized patient. This will then return clinical care to bedside administration and/or delays in patient care within California. It will also open decentralized pharmacy sites to financial pressures to terminate such practices, which is also not in the best interest of California patients. Finally, we would like to point out that for the most part the compounding violations that the Board has been recently citing involve preparations that are being made for future use. It is the storage of these compounded products that has caused any breach of aseptic technique to become clinically significant. This too points to the need to address compounded sterile products for immediate administration differently than compounded sterile products for future use	Reject: The pending regulation is not asking or forcing anyone to compound at the bedside. Our regulations are our attempt to coming inline with 797 guidelines, but neither 797 or our regulations are forcing a central compounding area. Both allow for segregated compounding area and for immediate use. We disagree that the BOP been mostly citing issues with storage of future used products.
	McGuff Compounding Pharmacy Services, Inc William J. Blair, Pharm.D., MBA Vice President and Director of Pharmacy Services	In general, California Law and regulation should harmonize with the federal description of a drug that has been compounded, i.e. “Compounded Drug” or Compounded Drug Product”. (503A and 503B). This harmonization identifies that the finished product of compounding via prescription or order is a drug, with full recognition as a drug in federal law and regulation. To use words like ‘compounded preparation’ adds confusion to the market place and allows insurance companies to classify Compounded Drugs as something other than a drug. This also adds confusion to the media which may likely lead the media to mis-manage or mis-identify the regulatory environment in which these Compounded Drugs are made. “Preparation’ may also confuse patients as ‘preparation’ may not connote the same gravity as taking a drug.	Reject: Language not being used in regulation
Overall Recommendations (No Code Section)	Providence Heath & Services Southern California Region	Use existing best practices to support best quality outcomes: We urge the board to adopt regulations that reflect the best quality outcomes, and to codify the measures implemented by hospital pharmacies, as documented here, that already are protecting patient safety and are aligned with USP Chapter 797 guidelines. Provide enough time for compliance: The board should extend the timeframe for implementation and enforcement of the final rule to ensure hospital pharmacies are fully compliant with state building regulations and hospital licensure requirements, particularly if facility changes and construction are to be completed	Reject: While we understand the lengthily process of upgrading a hospital, these regulations have pending for over a year and it will likely be a year before they are in effect. These years should have provided enough time to have the planning processed started if not completed.
Acute Care Recommendations (No Code Section)	Providence Heath & Services Southern California Region	Avoid unnecessary definitions: Eliminate "low volume" in reference to the preparation of hazardous drugs in hospital pharmacies. Under this definition, Providence pharmacies will not be able to prepare life-saving therapies to patients, including chemotherapy, antiviral, and anti-rejection treatments. USP 797 guidelines do not define "low volume," and we are uncertain how the board came to define "five or less per week" as a sufficient dosage. Hospital pharmacies should continue to compound sterile drug and hazardous drug preparations under specified conditions in the proposed regulations, without compromising patient health and safety. Provide flexibility in location: Remove wording from the beyond use dating sections that require an ISO Class 5 PEC to be located in an ISO Class 7 buffer area with an ante-area. USP 797 allows for the specified beyond use dating to apply to low and medium risk level compounding performed within an operationally compliant CAI or CACI located outside of an ISO class 7 buffer area. Without the recommended changes, hospital pharmacies will be prevented from utilizing USP 797 beyond use dating when compounding within the guidelines using a CAI or CACI in a non-ISO Class 7 cleanroom.	Low Volume definition removed; however, reference remains pending USP 800 regulation.

Code Section	Commenter	Comment	Board Response
Add new section to Article 4.5, Division 17 of Title 16 of CCR	PharMEDium Services, LLC Rich Kruzynski	An entity may provide for human use, without a patient specific prescription, a non-patient specific sterile compounded drug preparation if the following conditions apply: (a) The entity is registered with the United States Food and Drug Administration as an outsourcing facility pursuant to section 503B of the Federal Food, Drug, and Cosmetic Act; and (b) The entity is licensed as a Sterile Compounding Facility with the California Board of Pharmacy.	Reject - Outsourcing facilities will be subject to separate licensing requirement (503b).
Comments outside of Scope of Regulation			
4127.1	PharMEDium Services, LLC Rich Kruzynski	(a) A pharmacy shall not compound sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy license from the board pursuant to this section. The license shall be renewed annually and is not transferable. (b) A license to compound sterile drug products shall be issued only to a location that is licensed as a pharmacy with the Board of Pharmacy or as a Human Drug Compounding Outsourcing Facility under Section 503B of the Federal Food, Drug and Cosmetic Act, and shall be issued only to the owner of the pharmacy or Outsourcing Facility licensed at that location.	Reject - Outsourcing facilities will be subject to separate licensing requirement (503b). Outside Scope of Regulation
1707.5(a)(4)(A-P)	Kaweah Delta Home Infusion Pharmacy Steven Schnitzler, Pharm D.	*When applicable, directions for use shall use one of the following phrases:….* Route of administration is not included in any of the recommended phrases – may want to add [insert appropriate route] to avoid confusion.	Reject: Outside Scope of Regulation
Title 24, Part 2 Chapter 12 1250.4(5)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Add the displacement airflow design as an acceptable alternative design. In this design there is no physical door (and pressure differentials) between the buffer and the ante-area. The displacement airflow design is described in USP Chapter 797: "For rooms providing a physical separation through the use of walls, doors, and pass-throughs, a minimum differential positive pressure of 0.02- to 0.05-inch water column is required. For buffer areas not physically separated from the ante-areas, the principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. Using displacement airflow typically requires an air velocity of 40 ft per minute or more from the buffer area across the line of demarcation into the ante-area." This type of cleanroom design was added to the definition of "cleanroom" in Section 1735.1, but was not added to the text of this regulation. Rationale: USP Chapter 797 articulates a well thought-out description of the sterile compounding environment and engineering controls, based on the input and experience of nationally respected clean room engineers.	Reject: Outside Scope of Regulation
Title 24, Part 2 Chapter 12 1250.4(5.3)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Recommendation: Change regulation to say "…..in an environment that is less clean than ISO Class 7 Concern: Ambiguous wording RE: exceeds ISO Class 7, e.g. does that mean cleaner than ISO Class 7, or less clean than ISO Class 7?	Reject: Outside Scope of Regulation

Code Section	Commenter	Comment	Board Response
Title 24, Part 2 Chapter 12 1250.4(6)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Concern #1: There is a need to clarify the exact requirements outlined in this Regulation. Two documents have been shared with the public appear to conflict with each other; The first document discusses the need for a negative pressure room for compounding hazardous drugs. The second document also describes the compounding of hazardous drugs in a positive pressure room. To be in concordance with USP Chapter 797, there needs to be an allowance for compounding a low volume of chemotherapy preparations within biological safety cabinets (utilizing closed system transfer devices) in positive pressure clean rooms that also contain other types of laminar air flow hoods. Consider a hospital pharmacy in which a low volume of inpatient chemotherapy is prepared, and where the clean room was remodeled following the original 2004 USP Chapter 797 standards. It would likely be a single clean room, with an ante area and a buffer area. That remodel probably cost up to $1 million, depending upon the size of the pharmacy. In order to meet the proposed regulation, this clean room would need to be remodeled again to provide a separate anteroom, positive pressure buffer room, and a negative pressure buffer room for preparing hazardous drugs (chemotherapy). This would cost approx. an additional $1 million per inpatient pharmacy. The cost is excessive when weighed against any potential incremental patient safety benefits. The current language also conflicts with another section of the draft language, 1751.8(e)(2). Instead, we propose the USP Chapter 797 language, with a caveat that “low volume” be defined, since the USP Chapter 797 language is subjective and not enforceable. “In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., Closed System Transfer Device within a BSC or CACI that is located in a non-negative pressure room) is acceptable.” We propose this definition: “A low volume is defined as less than or equal to a mean number of twenty doses per week, averaged over a period of one month.”	Reject: Outside Scope of Regulation
Title 24, Part 2 Chapter 12 1250.4(6)	Kaiser Permanente Steven Gray Doug O'Brien Don Kaplan	Concern #2: There needs to be an allowance for ambulatory/outpatient oncology pharmacies which do not currently meet this requirement, and prepare a high volume of chemotherapy (e.g. greater than twenty doses per week) for administration to patients in medical offices and clinics. These pharmacies are typically equipped with a Class II biological safety cabinet in a small ISO Class 7 clean room under positive pressure. It will be very costly and time-consuming to remodel these pharmacies. We propose that ambulatory/outpatient oncology pharmacies be given a five-year period to come into compliance with the negative pressure environment requirement.	Reject: Outside Scope of Regulation