Title 16. Board of Pharmacy
Repealed Regulation Text

Repeal Sections 1708.3, 1708.4, and 1708.5

~~1708.3. Radioactive Drugs.~~

~~A radioactive drug is any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act or a radioactive biological product as defined in 21 CFR 600.3(ee) which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug or biological product which is intended to be made radioactive. This definition includes non-radioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds, potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Section 4025, Business and Professions Code.~~

~~1708.4. Pharmacist Handling Radioactive Drugs.~~

~~A pharmacist handling radioactive drugs must be competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. He must have completed a nuclear pharmacy course and/or acquired experience in programs approved by the Board. Education and experience in non-approved programs may be granted partial or equivalent credit, if, in the opinion of the Board, such programs provide the level of competence as approved programs or the Nuclear Pharmacy Competency Statement adopted by the Board.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4021, 4022, 4025, 4036 and 4037, Business and Professions Code.~~

~~1708.5. Pharmacy Furnishing Radioactive Drugs.~~

~~A pharmacy furnishing radioactive drugs is any area, place or premises described in a permit issued by the board where radioactive drugs are stored, processed, compounded, repackaged, or dispensed. A pharmacy exclusively furnishing radioactive drugs shall be exempt from the patient consultation area requirements of Title 16 Cal. Code of Regulations Section 1714(a) unless the Board finds that the public health and safety require their application.~~

~~A pharmacist qualified under Section 1708.4 to furnish radioactive drugs shall be in the pharmacy whenever the furnishing of radioactive drugs occurs. All personnel involved in the furnishing of radioactive drugs shall be under the immediate and direct supervision of such a qualified pharmacist.~~

~~Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4008 and 4008.2, Business and Professions Code.~~

Repeal Sections 1735 through 1735.8

~~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 preparation from chemicals or bulk drug substances~~

~~(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s), 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) The parameters and requirements stated by Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile 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.~~

~~1735.1. Compounding Definitions.~~

~~(a) "Ante-area" means an area with ISO Class 8 or better air quality 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 cleanroom, and maintains air flows from clean to dirty areas. ISO Class 7 or better air quality is required for ante-areas providing air to a negative pressure room.~~

~~(b) "Beyond use date" means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).~~

~~(c) "Biological Safety Cabinet (BSC)" means a ventilated cabinet for compounding sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the~~

~~biological safety cabinet shall be appropriately removed by properly designed external building exhaust. This external exhaust should be dedicated to one BSC or CACI.~~
~~(d) "Bulk drug substance" means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, is an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.~~
~~(e) "Cleanroom or clean area or buffer area" means a room or area with HEPA-filtered air that provides ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located.~~
~~(1) For nonhazardous compounding a positive pressure differential of 0.02 to 0.05 inch water column relative to all adjacent spaces is required.~~
~~(2) For hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of between 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.~~
~~(f) "Compounding Aseptic Containment Isolator (CACI)" means a unidirectional HEPA-filtered airflow 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 hazardous drugs are prepared, the exhaust air from the isolator shall be appropriately removed by properly designed external building exhaust. This external exhaust should be dedicated to one BSC or CACI. Air within the CACI shall not be recirculated nor turbulent.~~
~~(g) "Compounding Aseptic Isolator (CAI)" means a form of isolator specifically designed for nonhazardous compounding of pharmaceutical ingredients or preparations while bathed with unidirectional HEPA-filtered air. 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) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Air within the CAI shall not be recirculated nor turbulent.~~
~~(h) "Controlled cold temperature" means 2 degrees to 8 degrees C (35 degrees to 46 degrees F).~~
~~(i) "Controlled freezer temperature" means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F) or at a range otherwise specified by the pharmaceutical manufacturer(s) for that product.~~
~~(j) "Controlled room temperature" means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).~~

~~(k) "Copy or essentially a copy" of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.~~
~~(l) "Daily" means occurring every day the pharmacy is operating, except when daily monitoring of refrigerator and freezer temperature are required, then daily means every 24 hours.~~
~~(m) "Displacement airflow method" means a concept which utilizes a low pressure differential high airflow principle to maintain segregation from the adjacent ante-area by means of specific pressure differentials. This principle of displacement airflow shall require an air velocity of 40 ft per minute or more, from floor to ceiling and wall to wall, from the clean area across the line of demarcation into the ante-area. The displacement concept may not be used to maintain clean area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, or for hazardous compounds.~~
~~(n) "Dosage unit" means a quantity sufficient for one administration to one patient.~~
~~(o) "Equipment" means items that must be calibrated, maintained or periodically certified.~~
~~(p) "First air" means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.~~
~~(q) "Gloved fingertip sampling" means a process whereby compounding personnel lightly press each fingertip and thumb of each hand onto appropriate growth media, which are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganisms.~~
~~(r) "Hazardous" means all anti-neoplastic agents identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge.~~
~~(s) "Integrity" means retention of potency until the beyond use date provided on the label, so long as the preparation is stored and handled according to the label directions.~~
~~(t) "Lot" means one or more compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s).~~
~~(u) "Media-fill test" means a test used to measure the efficacy of compounding personnel in aseptic techniques whereby compounding procedures are~~

~~mimicked using a growth-based media and then the resulting preparation is evaluated for sterility. The media-fill test must mimic the most complex compounding procedures performed by the pharmacy.~~
~~(v) "Non-sterile-to-sterile batch" means any compounded drug preparation containing two (2) or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient.~~
~~(w) "Parenteral" means a preparation of drugs administered in a manner other than through the digestive tract. It does not include topical, sublingual, rectal or buccal routes of administration.~~
~~(x) "Personal protective equipment" means clothing or devices that protect the employee from exposure to compounding ingredients and/or potential toxins and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.~~
~~(y) "Potency" means active ingredient strength within +/-10% (or the range specified in USP37NF32, 37th Revision, Through 2nd Supplement Effective December 1, 2014) of the labeled amount. Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products in a health care facility licensed under section 1250 of the Health and Safety Code are exempt from this definition. For those exempt, the range shall be calculated and defined in the master formula.~~
~~(z) "Preparation" means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.~~
~~(aa) "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. This definition does not include any hospital, pharmacy, or other facility, whether or not separately licensed, that may be affiliated with, adjacent to, or co-owned by, the prescriber's practice environment.~~
~~(ab) "Primary Engineering Control (PEC)" means a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic containment isolators.~~
~~(ac) "Process validation" means demonstrating that when a process is repeated within specified limits, the process will consistently produce preparations complying with predetermined requirements. If any aspect of the process is changed, the process would need to be revalidated.~~
~~(ad) "Product" means a commercially manufactured drug or nutrient evaluated for safety and efficacy by the FDA.~~
~~(ae) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.~~

(af) "Segregated sterile compounding area" means a designated space for sterile-to-sterile compounding where a PEC is located within either a demarcated area (at least three foot perimeter) or in a separate room. Such area or room 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. The segregated sterile compounding area shall not have a sink, other than an emergency eye-washing station, located within three feet of a PEC. The segregated sterile compounding area shall be restricted to preparation of sterile-to-sterile compounded preparations.

(1) The BUD of a sterile drug preparation made in a segregated sterile compounding area is limited to 12 hours or less as defined by section 1751.8(d).

(2) When the PEC in the segregated sterile compounding area is a CAI or a CACI and the documentation provided by the manufacturer shows it meets the requirements listed in section 1751.4(f)(1)-(3), the assigned BUD shall comply with section 1751.8(a-b) or (d).

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

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4029, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

1735.2. Compounding Limitations and Requirements; Self-Assessment.

(a) Except as specified in (b) and (c), no drug 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 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 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.

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

(1) Is ordered by the prescriber or the prescriber's agent 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 office administration; and

~~(2) Is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; and~~
~~(3) Is sufficient for administration or application to patients solely in the prescriber's office, or for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to the prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; and~~
~~(4) That the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice; and~~
~~(5) With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to all prescribers to whom the pharmacy furnishes, 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 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 an 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 commercially available 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, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.~~
~~(e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:~~
~~(1) Active ingredients to be used.~~
~~(2) Equipment to be used.~~
~~(3) The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.~~
~~(4) Inactive ingredients to be used.~~
~~(5) Specific and essential compounding steps 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.~~

~~(8) Instructions for storage and handling of the compounded drug preparation.~~
~~(f) Where a pharmacy does not routinely compound a particular drug preparation, the master formula record for that preparation may be recorded on the prescription document itself.~~
~~(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.~~
~~(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.~~
~~(i) Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.~~
~~(1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:~~
~~(A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,~~
~~(B) the chemical stability of any one ingredient in the compounded drug preparation,~~
~~(C) the chemical stability of the combination of all ingredients in the compounded drug preparation,~~
~~(D) for non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,~~
~~(E) for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and~~
~~(F) for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation.~~
~~(G) A pharmacist, using his or her professional judgment may establish an extended date as provided in (D), (E), and (F), if the pharmacist researches by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision, and maintains documentation of the research, analysis and conclusion. The factors the pharmacist must analyze include:~~
~~(i) the nature of the drug and its degradation mechanism,~~
~~(ii) the dosage form and its components,~~
~~(iii) the potential for microbial proliferation in the preparation,~~

~~(iv) the container in which it is packaged,~~
~~(v) the expected storage conditions, and~~
~~(vi) the intended duration of therapy.~~
~~Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.~~
~~(2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:~~
~~(A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,~~
~~(B) The chemical stability of any one ingredient in the sterile compounded drug preparation,~~
~~(C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and~~
~~(D) The beyond use date assigned for sterility in section 1751.8.~~
~~(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:~~
~~(A) Method Suitability Test,~~
~~(B) Container Closure Integrity Test, and~~
~~(C) Stability Studies~~
~~(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.~~
~~(5) Shorter dating than set forth in this subdivision may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.~~
~~(j) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug preparation.~~
~~(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 (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 1/22.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. 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 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, both active and inactive, 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.~~
~~(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.~~
~~Authority cited: Sections 4005 and 4127, Business and Professions Code.~~
~~Reference: Sections 4005, 4029, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.~~

~~1735.3. Recordkeeping of Compounded Drug Preparations.~~
~~(a) For each compounded drug preparation, pharmacy records shall include:~~
~~(1) The master formula document.~~
~~(2) A compounding log consisting of a single document containing all of the following:~~
~~(A) Name and Strength of the compounded drug preparation.~~
~~(B) The date the drug preparation was compounded.~~
~~(C) The identity of any pharmacy personnel engaged in compounding the drug preparation.~~
~~(D) The identity of the pharmacist reviewing the final drug preparation.~~
~~(E) The quantity of each ingredient used in compounding the drug preparation.~~
~~(F) 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. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply.~~
~~(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile preparations compounded in a single lot for administration within seventy-two (72) hours to a patient 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.~~
~~(G) A pharmacy-assigned unique reference or lot number for the compounded drug product preparation.~~
~~(H) The beyond use date or beyond use date and time of the final compounded drug preparation, expressed in the compounding document in a standard date and time format.~~

~~(I) The final quantity or amount of drug preparation compounded for dispensing.~~
~~(J) Documentation of quality reviews and required post-compounding process and procedures.~~
~~(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 ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug products used to compound drug preparations shall be obtained, whenever possible, from FDA-registered suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products 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 last in effect. 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.~~

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

~~(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:~~
~~(1) Name of the compounding pharmacy and dispensing pharmacy (if different);~~
~~(2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;~~
~~(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;~~
~~(4) The beyond use date for the drug preparation;~~
~~(5) The date compounded; and~~
~~(6) The lot number or pharmacy reference number.~~
~~(b) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5.~~

~~(c) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a statement that the drug has been compounded by the pharmacy.~~
~~(d) Prior to dispensing drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a), (b), and (c) 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), strength, volume or weight of the preparation, pharmacy reference or lot number, and beyond use date, and shall not be subject to minimum font size requirements. Once dispensed, outer packaging must comply with 1735.4(a) – (c).~~
~~(e) All hazardous agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "Hazardous – Dispose of Properly."~~
~~Authority cited: Sections 4005 and 4127, Business and Professions Code.~~
~~Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.~~

~~1735.5. Compounding Policies and Procedures.~~
~~(a) Any pharmacy engaged in compounding shall maintain written policies and procedures 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. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.~~
~~(b) The policies and procedures shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated whenever changes in policies and procedures are implemented.~~
~~(c) The policies and procedures shall include at least the following:~~
~~(1) Procedures for notifying staff assigned to compounding duties of any changes in policies or procedures.~~
~~(2) A written plan for recall of a dispensed compounded drug preparation where subsequent information demonstrates the potential for adverse effects with continued use. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).~~
~~(3) 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.~~
~~(4) 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.
(5) Documentation of the methodology used to validate integrity, potency, quality, and labeled strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.
(6) Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.
(7) Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.
(8) Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.
(9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.
(10) 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 within the pharmacy.
(11) Policies and procedures for proper garbing when compounding with hazardous products. This shall include when to utilize double shoe covers.
Authority cited: Sections 4005 and 4127, Business and Professions Code.
Reference: Sections 4005, 4036, 4037, 4051, 4052, 4127 and 4301, Business and Professions Code

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 compounding of compounded drug preparations. This shall include records of maintenance and cleaning of the facilities and equipment. Where applicable, this shall also include records of certification(s) of facilities or equipment.
(b) Any equipment used to compound drug preparations shall be stored, used, maintained, and cleaned in accordance with manufacturers' specifications.
(c) Any equipment that weighs, measures, or transfers ingredients used to compound drug preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy. Documentation of each such calibration shall be recorded in a form which is not alterable and these records of calibration shall be maintained and retained in the pharmacy.
(d) Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs.

(e) Hazardous drug compounding shall be completed in an externally exhausted physically separate room with the following requirements:
(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hours or less or when non sterile products are compounded; and
(2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and
(3)(A) For sterile compounding, each BSC or CACI shall be externally exhausted.
(B) For nonsterile compounding, a BSC, a CACI, or other containment ventilated enclosure shall be used and shall either use a redundant HEPA filter in series or be externally exhausted. For purposes of this paragraph, a containment ventilated enclosure means a full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.
(4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.
(f) Where compliance with the January 1, 2017 amendments to Article 4.5 or Article 7, requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.
Authority cited: Sections 4005 and 4127, Business and Professions Code.
Reference: Sections 4005, 4029, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

1735.7. Training of Compounding Staff.
(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding process.
(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 preparation.~~
~~Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code~~

~~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 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 analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.~~
~~(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug preparation is ever discovered to be outside 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 within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing.~~
~~Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.~~

Repeal Article 7 and Sections 1751 through 1751.10
~~Article 7. Sterile Compounding~~
~~1751. Sterile Compounding; Compounding Area; Self-Assessment.~~
~~(a) Any pharmacy engaged in compounding sterile drug 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 compounding.~~

~~(b) Any pharmacy compounding sterile drug preparations shall have a compounding area designated for the preparation of sterile drug preparations that is in a restricted location where traffic has no impact on the performance of the PEC(s). The cleanroom, including the walls, ceilings, and floors, shall be constructed in accordance with Section 1250.4 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 505.5 of Title 24, Part 4, Chapter 5 of the California Code of Regulations. The environments within the pharmacy shall meet the following standards:~~

~~(1) Each ISO environment shall be certified at least every six months by a qualified technician in accordance with Section 1751.4. Certification records must be retained in the pharmacy.~~

~~(2) Items related to the compounding of sterile drug preparations within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.~~

~~(3) A sink shall be included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains shall not be present in any ISO Class 7 or better cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 or better PEC, with the exception of emergency eye-rinsing stations. A sink may be located in an ante-area. When the PEC in the segregated sterile compounding area is a CAI or CACI and the documentation provided by the manufacturer shows it meets the requirements listed in 1751.4(f)(1)-(3) the sterile compounding area is exempt from the room requirement listed in 1751(b)(3).~~

~~(4) There shall be a refrigerator and, where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing, and a backup plan to ensure continuity of available compounded drug preparations in the event of a power outage.~~

~~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.~~

~~1751.1. Sterile Compounding Recordkeeping Requirements.~~

~~(a) In addition to the records required by section 1735.3, any pharmacy engaged in any compounding of sterile drug preparations shall maintain the following records, which must be readily retrievable, within the pharmacy:~~

~~(1) Documents evidencing training and competency evaluations of employees in sterile drug preparation policies and procedures.~~

~~(2) Results of hand hygiene and garbing assessments 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 tests.~~
~~(4) Results of viable air and surface sampling.~~
~~(5) Biannual video of smoke studies in all ISO Class 5 certified spaces.~~
~~(6) Documents indicating daily documentation of room, refrigerator, and freezer temperatures appropriate for sterile compounded drug preparations consistent with the temperatures listed in section 1735.1 for:~~
~~(A) Controlled room temperature.~~
~~(B) Controlled cold temperature.~~
~~(C) Controlled freezer temperature.~~
~~(7) Certification(s) of the sterile compounding environment(s).~~
~~(8) Documents indicating daily documentation of air pressure differentials or air velocity measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity measurements between all rooms or spaces with an immediate entry or opening to ISO rooms or areas.~~
~~(9) Other facility quality control records specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).~~
~~(10) Logs or other documentation of inspections for expired or recalled chemicals, bulk drug substances, drug products, or other ingredients.~~
~~(11) Preparation records including the master formula document, the preparation compounding log, and records of end-product evaluation testing and 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, lot number, and amount of any drug preparation compounded for future use, the date on which any preparation was provided to a prescriber, and the name, address, license type and number of the 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, 4029, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.~~

~~1751.2. Sterile Compounding Labeling Requirements.~~

~~In addition to the labeling information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, sections 1707.5~~

and 1735.4, a pharmacy that compounds sterile drug preparations shall include the following information on the labels for each such preparation:
(a) The telephone number of the pharmacy. The telephone number is not required on the label for sterile drug preparations administered to inpatients within the hospital.
(b) Instructions for storage, handling, and administration.
(c) All hazardous agents shall bear a special label which states "Chemotherapy -Dispose of Properly" or "Hazardous – Dispose of Properly."
Authority cited: Sections 4005 and 4127, Business and Professions Code.
Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

1751.3. Sterile Compounding Policies and Procedures.
(a) Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:
(1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling and actions to be taken when the levels are exceeded.
(2) Airflow considerations and pressure differential monitoring.
(3) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.
(4) Cleaning and maintenance of ISO environments and segregated compounding areas.
(5) Compounded sterile drug preparation stability and beyond use dating.
(6) Compounding, filling, and labeling of sterile drug preparations.
(7) Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.
(8) Depyrogenation of glassware (if applicable)
(9) Facility management including certification and maintenance of controlled environments and related equipment.
(10) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.
(11) Hand hygiene and garbing.
(12) Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.
(13) Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.
(14) Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and

~~knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique, demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.~~

~~(15) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.~~

~~(16) Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.~~

~~(17) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.~~

~~(18) Proper use of equipment and supplies.~~

~~(19) Quality assurance program compliant with sections 1711, 1735.8 and 1751.7.~~

~~(20) Record keeping requirements.~~

~~(21) Temperature monitoring in compounding and controlled storage areas.~~

~~(22) The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.~~

~~(23) Use of automated compounding devices (if applicable).~~

~~(24) Visual inspection and other final quality checks of sterile drug preparations.~~

~~(b) For lot compounding, the pharmacy shall maintain written policies and procedures that includes, in addition to the elements required by section 1735.5 and 1751.3(a), written policies and procedures regarding the following:~~

~~(1) Use of master formula documents and compounding logs.~~

~~(2) Appropriate documentation.~~

~~(3) Appropriate sterility and potency testing.~~

~~(c) For non-sterile-to-sterile batch compounding, the pharmacy shall maintain written policies and procedures for compounding that includes, in addition to the elements required by section 1735.5, 1751.3(a), and 1751.7(e), written policies and procedures regarding the following:~~

~~(1) Process validation for chosen sterilization methods.~~

~~(2) End-product evaluation, quantitative, and qualitative testing.~~

~~(d) Policies and procedures shall be immediately available to all personnel involved in compounding activities and to board inspectors.~~

~~(e) All personnel involved must read the policies and procedures before compounding sterile drug preparations. All personnel involved must read all additions, revisions, and deletions to the written policies and procedures. Each review must be documented by a signature and date.~~

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

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

~~(a) No sterile drug 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 drug preparations.~~

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

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

~~(d) Cleaning shall be done using a germicidal detergent and sterile water. The use of a sporicidal agent is required to be used at least monthly.~~

~~(1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, work table surfaces, carts, and counters.~~

~~(2) Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment shall be cleaned at least monthly.~~

~~(3) Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.~~

~~(4) All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.~~

~~(e) Disinfection, using a suitable sterile agent, shall also occur on all surfaces in the ISO Class 5 PEC frequently, including:~~

~~(1) At the beginning of each shift;~~

~~(2) At least every 30 minutes when compounding involving human staff is occurring or before each lot;~~

~~(3) After each spill; and~~

~~(4) When surface contamination is known or suspected.~~

~~(f) Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. 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-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Certification records must be retained for at least 3 years. Unidirectional compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 cleanroom if the isolator is certified to meet 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 that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom 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 sterile hazardous agents shall do so in accordance with Section 505.7 .1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a negative pressure PEC. Additionally, each PEC used to compound hazardous agents shall be externally vented. The negative pressure PEC must be certified every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Any drug preparation that is compounded in a PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous.~~

~~(1) During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur. Garbing shall include hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two pairs of sterile ASTM D6978-05 standard gloves.~~

~~(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) Compounding aseptic isolator and compounding aseptic containment isolator used in the compounding of sterile drug preparations shall use non-turbulent unidirectional air flow patterns. A smoke patterned test shall be used to determine air flow patterns.~~

~~(j) Viable surface sampling shall be done at least every six months for all sterile-to-sterile compounding and quarterly for all non-sterile-to-sterile compounding. Viable air sampling shall be done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and shall be done at least once every six months. Viable surface and viable 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. Viable 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 pursuant to its policies and procedures. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operations and facility management.~~

~~(k) The sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which typically 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.~~

~~(l) A licensee may request a waiver of these provisions as provided in section 1735.6(f).~~

~~Authority Cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4029, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code; and Section 18944, Health and Safety Code.~~

~~1751.5. Sterile Compounding Attire.~~

~~(a) When compounding sterile drug preparations the following standards must be met:~~

~~(1) Personal protective equipment consisting of a non-shedding gown, head cover, face mask, facial hair covers (if applicable), and shoe covers must be worn inside the designated area at all times. For hazardous compounding double shoe covers are required.~~

~~(2) Personal protective equipment must be donned and removed in an ante-area or 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.~~

~~(4) Compounding personnel shall not wear any wrist, hand, finger, or other visible jewelry, piercing, headphones, earbuds, or personal electronic device.~~

~~(5) 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 cleanroom. 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 exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, nail polish, or artificial nails shall be excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.~~

~~(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.~~

~~1751.6. 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 drug preparations and related supplies furnished by the pharmacy.~~

~~(b) The pharmacist-in-charge shall ensure that all pharmacy personnel engaging in compounding sterile drug preparations have training and demonstrated competence in the safe handling and compounding of sterile drug preparations, including hazardous agents if the pharmacy compounds products with 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 drug preparations.~~

~~(e) Pharmacies that compound sterile drug 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 preparation compounding documentation.~~
~~(D) Quality assurance procedures.~~
~~(E) Aseptic preparation procedures.~~
~~(F) Proper hand hygiene, gowning and gloving technique.~~
~~(G) General conduct in the controlled area (aseptic area practices).~~
~~(H) Cleaning, sanitizing, and maintaining of the equipment and 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 engaged in sterile compounding must successfully complete practical skills training in aseptic technique and aseptic area practices using models that are comparable to the most complex manipulations to be performed by the individual. Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations. 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.~~

~~1751.7. Sterile Compounding Quality Assurance and Process Validation.~~
~~(a) Any pharmacy engaged in compounding sterile drug 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 quality assurance program shall include at least the following:~~
~~(1) Procedures for cleaning and sanitization of the sterile preparation area.~~
~~(2) Actions to be taken in the event of a drug recall.~~

~~(3) Documentation justifying the chosen beyond use dates for compounded sterile drug preparations.~~

~~(b)(1) The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug 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 the types of manipulations, products and batch sizes the individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing. Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then each individual's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.~~

~~(2) Each individual's competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile preparations from non-sterile ingredients.~~

~~(3) The pharmacy's validation process on aseptic technique and aseptic area practices must be revalidated whenever:~~

~~(A) the quality assurance program yields an unacceptable result,~~

~~(B) there is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes, but is not limited to, when the PEC is moved, repaired or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or when improper aseptic techniques are observed.~~

~~(4) The pharmacy must document the validation and revalidation process.~~

~~(c) All sterile compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, each individual who may be required to do so in practice must successfully complete a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug 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.~~

~~(e)(1) Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits, 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. Exempt from pyrogen testing are topical ophthalmic and inhalation preparations.~~

~~(2) The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens:~~

~~(A) Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.~~

~~(B) Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.~~

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

~~1751.8. Beyond Use Dating for Sterile Compounded Drug Preparations.~~

~~In conformity with and 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 does not exceed the shortest expiration date or beyond use date of any ingredient in sterile compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and that, 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 an extended beyond use date, conforms to the following limitations:~~

~~(a) The beyond use date shall specify that storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:~~

~~(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a~~

~~CAI which meets the requirements in 1751.4(f)(1)-(3), 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 or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing.~~

~~(b) The beyond use date shall specify that storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:~~

~~(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), 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.~~

~~(c) The beyond use date shall specify that storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, regardless of intervening sterilization of that ingredient and the following applies:~~

~~(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3).~~

~~(d) The beyond use date shall specify that storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:~~

~~(1) The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile 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.~~

~~(e) 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 (d), 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. A PEC used solely to compound 'immediate use' preparations need not be placed within an ISO Class 7 cleanroom, with an ante-area. 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.**

~~(f) The beyond use date for any compounded allergen extracts shall be the earliest manufacturer expiration date of the individual allergen extracts.~~

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

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

~~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~~

~~shall be labeled with a beyond use date and 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. A container must remain within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.~~

~~(3) If the puncture time is not noted on the container, the container must immediately be discarded.~~

~~(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 shall be labeled with a beyond use date and 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 storage circumstance. If any open container is not labeled with a beyond use date or the beyond use date is not correct, the container must immediately be discarded.~~

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

~~1751.10. Sterile Compounding Reference Materials.~~

~~In any pharmacy engaged in compounding sterile drug preparations, there shall be current and appropriate reference materials regarding the compounding of sterile drug 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.~~