

DEPARTMENT OF CONSUMER AFFAIRS  
BOARD OF PHARMACY

To Repeal Title 16 CCR §§ 1716.1 and 1716.2,  
Adopt Title 16 CCR §§ 1735 – 1735.8 And  
Amend Title 16 CCR §§ 1751 – 1751.8 Regarding Requirements for Compounding

Repeal Section 1716.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**§1716.1. Compounding Unapproved Drugs for Prescriber Office Use.**

As used in Business and Professions Code Section 4052(a)(1), the following terms have the indicated meaning concerning the compounding of unapproved drugs for prescriber office use:

- (a) "Reasonable quantity" means that quantity of an unapproved drug which:
  - (1) is sufficient for that prescriber's office use consistent with the expiration date of the product as set forth in section 1716.2(a)(3); and
  - (2) is reasonable considering the intended use of the compounded medication and nature of the prescriber's practice; and
  - (3) 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 identity, strength, quality and purity of the compounded medication.
- (b) "Compounded medication" means medications actually compounded by the pharmacy supplying them to a prescriber.
- (c) "Prescriber office use" means application or administration in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4027, 4033, 4050, 4051, 4052, 4059, 4170 and 4171, Business and Professions Code.

Repeal Section 1716.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**§1716.2. Record Requirements—Compounding for Future Furnishing.**

- (a) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:
  - (1) The date of preparation.
  - (2) The lot numbers. These may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If the lot number is assigned by the pharmacy, the pharmacy must also record the original manufacturer's lot numbers and expiration dates, if known. If the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components.
  - (3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.
  - (4) The signature or initials of the pharmacist performing the compounding.
  - (5) A formula for the compounded product. The formula must be maintained in a readily retrievable form.

Changes to the regulatory text are indicated. For the 2<sup>nd</sup> 15-day comment period, deletions to the regulatory text are indicated by double strike-through italics, thus: ~~deleted language~~. Additions to the regulatory text are indicated by double underline italics, thus: added language.

- (6) ~~The name(s) of the manufacturer(s) of the raw materials.~~
- (7) ~~The quantity in units of finished products or grams of raw materials.~~
- (8) ~~The package size and the number of units prepared.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, 4059, 4081 and 4332, Business and Professions Code.~~

### Article 4.5 Compounding

Add Section 1735 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 drug product 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 tablet splitting 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 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.

Add Section 1735.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

#### §1735.1. Compounding Definitions

- (a) “Integrity” means retention of potency until the expiration date noted on the label.
- (b) “Potency” means active ingredient strength within +/- 10% of the labeled amount.
- (c) “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.
- (d) “Strength” means amount of active ingredient per unit of a compounded drug product.

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

Add Section 1735.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**§1735.2. Compounding Limitations and Requirements**

- (a) Except as specified in (b) and (c), no drug product 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 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 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) Pursuant to Business and Professions Code section 4052(a)(1), a “reasonable quantity” of compounded drug product may be furnished to a prescriber for office use upon prescriber order, where “reasonable quantity” is that amount of compounded drug product that:
  - (1) is sufficient for administration or application to patients in the prescriber’s office, or for distribution of not more than a 72-hour supply to the prescriber’s patients, as estimated by the prescriber; and
  - (2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and
  - (3) 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.
- (d) A drug product 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) Inactive ingredients to be used.
  - (3) Process and/or procedure used to prepare the drug.
  - (4) Quality reviews required at each step in preparation of the drug.
  - (5) Post-compounding process or procedures required, if any.
  - (6) Expiration dating requirements.
- (e) Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.
- (f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.
- (g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.
- (h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising

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the compounding, it should not be used. This “beyond use date” of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products 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) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.
- (j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board (form 17m-39 rev. 10/07). 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 odd-numbered each year, within 30 days of the start of a new pharmacist-in-charge, 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.

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

Add Section 1735.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**§1735.3. Records of Compounded Drug Products**

- (a) For each compounded drug product, the pharmacy records shall include:
  - (1) The master formula record.
  - (2) The date the drug product was compounded.
  - (3) The identity of the pharmacy personnel who compounded the drug product.
  - (4) The identity of the pharmacist reviewing the final drug product.
  - (5) The quantity of each component used in compounding the drug product.
  - (6) The manufacturer 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 compounded on a one-time basis for administration within ~~two~~*twenty-four* hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.
  - (7) The equipment used in compounding the drug product.
  - (8) A pharmacy assigned reference or lot number for the compounded drug product.
  - (9) The expiration date of the final compounded drug product.
  - (10) The quantity or amount of drug product compounded.
- (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) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug

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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.

- (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.

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

Add Section 1735.4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**§1735.4. Labeling of Compounded Drug Products**

- (a) In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product 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 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(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy reference or lot number, and expiration date.

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

Add Section 1735.5 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.
- (b) The policy and procedure manual shall be reviewed 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) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.
  - (3) 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.

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- (4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.
- (5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

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

Add Section 1735.6 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. Where applicable, this shall include records of certification(s) of facilities or equipment.
- (b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications.
- (c) Any equipment used to compound drug products for which calibration or adjustment is appropriate shall be calibrated prior to use 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.

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

Add Section 1735.7 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.

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

Add Section 1735.8 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.
- (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. All qualitative and quantitative analysis reports for compounded drug products 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 is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.

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

## Article 7 Sterile Injectable Compounding

Amend Section 1751 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

### §1751. Sterile Injectable Compounding; Compounding Area.

- (a) Any pharmacy engaged in compounding sterile injectable drug products 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) The Any pharmacy doing sterile injectable compounding shall have a designated area for the preparation of sterile injectable products which shall meet the following standards:
- (1) Clean Room and Work Station Requirements, shall be in accordance with Section 490A.3.1 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
  - (2) Walls, ceilings and floors shall be constructed in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
  - (3) Be ventilated in a manner in accordance with Section 505.12 of Title 24, Part 4, Chapter 5 of the California Code of Regulations.
  - (4) Be certified annually 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. Certification records must be retained for at least 3 years.
  - (5) The pharmacy shall be arranged in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.
  - (6) A sink shall be included in accordance ~~in~~ with Section 490A.3.4 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
  - (7) There shall be a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.
- (c) Any pharmacy compounding a sterile injectable product 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; and Section 18944(a), Health and Safety Code.

Renumber section 1751.3 to new section 1751.1 and amend section 1751.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**§1751.3. 1751.1. Sterile Injectable Recordkeeping Requirements.**

- (a) Pharmacies compounding sterile injectable products for future use pursuant to section ~~1716.1~~ 1735.2 shall, in addition to those records required by section ~~1716.2~~ 1735.3, have 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 subdivisions (a), for sterile products compounded from one or more non-sterile ingredients, the following records must be ~~maintained for at least three years~~ made and kept by the pharmacy:
  - (1) The training and competency evaluation of employees in sterile product procedures.
  - (2) Refrigerator and freezer temperatures.
  - (3) Certification of the sterile compounding environment.
  - (4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).
  - (5) Inspection for expired or recalled pharmaceutical products or raw ingredients.
  - (6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.
- (c) ~~Pharmacies shall maintain records of validation processes as required by Section 1751.7~~ (b) for three years 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.

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

Amend Section 1751.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**§1751.2. Sterile Injectable Labeling Requirements.**

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

- (a) Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.
- (b) Name and concentrations of ingredients contained in the sterile injectable product.
- (c) Instructions for storage and handling.
- (d) All cytotoxic agents shall bear a special label which states "Chemotherapy -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.

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Renumber section 1751.02 to new section 1751.3 and amend section 1751.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**§1751.02. 1751.3. Sterile Injectable Policies and Procedures.**

- (a) ~~Written policies and procedures associated with the pharmacy's preparation and dispensing of sterile injectable products shall include, but not be limited to~~ Any pharmacy engaged in compounding sterile injectable drug products 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.
  - (2) Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.
  - (3) Equipment and supplies.
  - (4) Training of staff in the preparation of sterile injectable products.
  - (5) Procedures for handling cytotoxic agents.
  - (6) Quality assurance program.
  - (7) 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 products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic 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 products 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 products, 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) Competency evaluation.
    - (B) Storage and handling of products and supplies.
    - (C) Storage and delivery of final products.
    - (D) Process validation.
    - (E) Personnel access and movement of materials into and near the controlled area.
    - (F) Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).
    - (G) Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. 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.

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- (H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.
- (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.
- (J) Sterilization.
- (K) End-product evaluation and testing.

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

Re-number section 1751.01 to new section 1751.4 and amend section 1751.4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**§1751.01. 1751.4. Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients.**

- (a) No sterile injectable product shall be ~~prepared~~ 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.
- (b) During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired.
- (c) All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected.
- (d) 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.
- (e) Pharmacies preparing parenteral cytotoxic agents shall be do so in accordance with Section 4-1106(b) of Title 24 of the California Administrative Code, requiring a laminar air flow hood. The hood must be certified annually 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 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. Certification records must be retained for at least 3 years.

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(a), Health and Safety Code.

Repeal Section 1751.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**§1751.1. Laminar Flow Biological Safety Cabinet.**

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Pharmacies preparing parenteral cytotoxic agents shall be in accordance with Section 4-1106(b) of Title 24 of the California Administrative Code. The hood must be certified annually 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 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. Certification records must be retained for at least 3 years.

Authority cited: ~~Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code; and Section 18944(a), Health and Safety Code.~~

Repeal Section 1751.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**~~§1751.3. Recordkeeping Requirements.~~**

- (a) ~~Pharmacies compounding sterile injectable products for future use pursuant to section 1716.1 1735.2 shall, in addition to those records required by section 1716.2 1735.3, have 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 subdivisions (a), for sterile products compounded from one or more non-sterile ingredients the following records must be maintained for at least three years:~~
- ~~(1) The training and competency evaluation of employees in sterile product procedures.~~
  - ~~(2) Refrigerator and freezer temperatures.~~
  - ~~(3) Certification of the sterile compounding environment.~~
  - ~~(4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).~~
  - ~~(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.~~
  - ~~(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.~~
- (c) ~~Pharmacies shall maintain records of validation processes as required by Section 1751.7 (b) for three years.~~

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

Renumber section 1751.4 to new section 1751.5 and amend section 1751.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**~~§1751.4. 1751.5. Sterile Injectable Compounding Attire.~~**

- (a) When preparing cytotoxic agents, gowns and gloves shall be worn.
- (b) When compounding sterile products from one or more non-sterile ingredients the following standards must be met:

Changes to the regulatory text are indicated. For the 2<sup>nd</sup> 15-day comment period, deletions to the regulatory text are indicated by double strike-through italics, thus: ~~deleted language~~. Additions to the regulatory text are indicated by double underline italics, thus: added language.

- (1) Cleanroom garb consisting of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times.
- (2) Cleanroom garb must be donned and removed outside the designated area.
- (3) Hand, finger, and 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.

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

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

Renumber section 1751.5 to new section 1751.6 and amend section 1751.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**§1751.5, 1751.6. Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.**

- (a) Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.
- (b) The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, including cytotoxic agents if the pharmacy compounds products with cytotoxic 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 products.
- (e) Pharmacies that compound sterile products from one or more non-sterile ingredients 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 compounding documentation.
    - (D) Quality assurance procedures.
    - (E) Aseptic preparation procedures.
    - (F) Proper gowning and gloving technique.
    - (G) General conduct in the controlled area.
    - (H) Cleaning, sanitizing, and maintaining equipment used in the controlled area.
    - (I) Sterilization techniques.
    - (J) Container, equipment, and closure system selection.

Changes to the regulatory text are indicated. For the 2<sup>nd</sup> 15-day comment period, deletions to the regulatory text are indicated by double strike-through italics, thus: ~~deleted language~~. Additions to the regulatory text are indicated by double underline italics, thus: added language.

- (2) Each person assigned to the controlled area 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 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.

Repeal Section 1751.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**§1751.6. Disposal of Waste Material.**

~~Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The procedures shall include cleanup of spills and shall be in conformance with local health jurisdiction.~~

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

Amend 1751.7 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 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. ~~There shall be 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) Cleaning and sanitization of the parenteral medication preparation area.
  - (2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.
  - (3) Actions to be taken in the event of a drug recall.
  - (4) Written justification of the chosen expiration dates for compounded sterile injectable products.
- (b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used

Changes to the regulatory text are indicated. For the 2<sup>nd</sup> 15-day comment period, deletions to the regulatory text are indicated by double strike-through italics, thus: ~~deleted language~~. Additions to the regulatory text are indicated by double underline italics, thus: added language.

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 same personnel, procedures, equipment, and materials are must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is 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) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients 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.
- (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.

Renumber section 1751.9 to new section 1751.8 and amend section 1751.8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**§1751.9. 1751.8. Sterile Injectable Compounding Reference Materials.**

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