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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment

The California Code of Regulations section 1735.2 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code that compounds drug preparations to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever: (1) a new pharmacy permit has been issued; or (2) there is a change in the pharmacist-in-charge; or (3) there is a change in the licensed location of the pharmacy. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be completed in its entirety and may be completed online, printed, readily retrievable and retained in the pharmacy. Do not copy a previous assessment.

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Fax: _____

Ownership: ☐Sole Owner ☐Partnership ☐Corporation ☐LLC
☐Non-Licensed Owner ☐Other (please specify) _____

License #: _____ Exp. Date: _____ Other License #: _____ Exp. Date: _____

Licensed Sterile Compounding License # _____ Expiration: _____

Accredited by: _____ From: _____ To: _____

Centralized Hospital Packaging License #: _____ Exp. Date: _____

Hours: Weekdays _____ Sat_____ Sun. _____ 24 Hours _____

PIC: _____ RPH # _____ Exp. Date: _____

Website address (optional): _____

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians assigned to compounding duties): (Please use additional sheets if necessary)

1. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

2. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

3. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

4. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

5. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

6. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

7. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

8. _____ INT # _____ Exp. Date: _____

9. _____ INT # _____ Exp. Date: _____

10. _____ INT # _____ Exp. Date: _____

11. _____ TCH # _____ Exp. Date: _____

12. _____ TCH # _____ Exp. Date: _____

13. _____ TCH # _____ Exp. Date: _____

14. _____ TCH # _____ Exp. Date: _____

15. _____ TCH # _____ Exp. Date: _____

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PIC Initials

Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

ALL COMPOUNDING PHARMACIES Complete Sections 1 through 10.

1. Definitions (CCR 1735 and 1735.1)

Yes No N/A

☐ ☐ ☐ 1.1 The pharmacy compounds as defined in CCR 1735(a).

☐ ☐ ☐ 1.2 Each pharmacist, intern pharmacist, and pharmacy technician involved with compounding understands the definitions in CCR 1735.1.

2. Compounding Limitations and Requirements (CCR 1735.2)

Yes No N/A

☐ ☐ ☐ 2.1. The pharmacy does not compound drug preparations prior to receipt of a valid prescription unless under the following conditions, as allowed in CCR 1735.2 (b-c) (CCR 1735.2[a]). See sections 2.2 and 2.3

☐ ☐ ☐ 2.2. The pharmacy prepares and stores a limited quantity of a compounded drug preparations in advance of receipt of a patient specific prescription solely in such quantity as is necessary to ensure continuity of care of an identified population as defined in CCR 1735.2(b).

☐ ☐ ☐ 2.3. The pharmacy compounds a reasonable quantity of drug preparations which is furnished to a prescriber for office use upon prescriber order as allowed in CCR 1735.2(c) and under all of the following requirements:

- ☐ 2.3.1. Is ordered by the prescriber or the prescribers' agent on 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 sufficient for office administration; (CCR 1735.2[c][1]) **AND**
- ☐ 2.3.2. Is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; (CCR 1735.2[c][2]) **AND**
- ☐ 2.3.3. Is sufficient for administration or application to patients in the prescriber's office or for distribution of not more than a 120-hour supply for veterinary medical practices; (CCR 1735.2[c][3]) **AND**
- ☐ 2.3.4. The pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded preparation and the nature of the prescriber's practice; (CCR 1735.2[c][4]) **AND**

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☐ 2.3.5. 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; (CCR 1735.2[c][5]) **AND**

☐ 2.3.6. Does not exceed an amount the pharmacy can reasonably and safely compound. (CCR 1735.2[c][6])

Yes No N/A

☐ ☐ ☐ 2.4. The pharmacy does NOT compound drug preparations that: (CCR 1735.2[d])

☐ 2.4.1. Are classified by the FDA as demonstrably difficult to compound; (CCR 1735.2[d][1])

☐ 2.4.2. Appear on an FDA list of drugs that have been withdrawn or removed from the market; (CCR 1735.2[d][2]) or

☐ 2.4.3. Are copies or essentially copies of one or more commercially available drug products. (CCR 1735.2[d][3])

☐ ☐ ☐ 2.5. The pharmacy does not compound drug preparations until it has prepared a written master formula document that includes the following elements: (CCR 1735.2[e][1-8])

☐ 2.5.1. Active ingredients used.

☐ 2.5.2. Equipment to be used.

☐ 2.5.3. Beyond use date (BUD).

☐ 2.5.4. Inactive ingredients used.

☐ 2.5.5. Specific and essential compounding steps.

☐ 2.5.6. Quality reviews required at each step.

☐ 2.5.7. Post-compounding process or procedures, if required.

☐ 2.5.8. Instructions for storage and handling.

☐ ☐ ☐ 2.6. The master formula for a drug preparation not routinely compounded by the pharmacy may be recorded on the prescription document itself. (CCR 1735.2[f])

☐ ☐ ☐ 2.7. The pharmacists performing or supervising compounding understand they are responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the BUD indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed. (CCR 1735.2[g])

☐ ☐ ☐ 2.8. All chemicals, bulk drug substances, drug products and other components used for drug compounding are stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality and labeled strength. (CCR 1735.2[h])

☐ ☐ ☐ 2.9. Every compounded drug preparation is given a BUD representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and is determined based on the professional judgment of the pharmacist performing or supervising the compounding. (CCR 1735.2[i])

☐ 2.9.1. For non-sterile compounded drug preparations, the BUD does not exceed any of the following: (CCR 1735.2[i][1][A-G])

- ☐ 2.9.1.1. The shortest expiration date or BUD of any ingredient in the compounded drug preparation,
- ☐ 2.9.1.2. The chemical stability of any one ingredient in the compounded drug preparation;
- ☐ 2.9.1.3. The chemical stability of the combination of all ingredients in the compounded drug preparation,
- ☐ 2.9.1.4. For non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,
- ☐ 2.9.1.5. For water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and
- ☐ 2.9.1.6. 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.
- ☐ 2.9.1.7. The pharmacist, using their professional judgment establishes 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.

☐ 2.9.2. For sterile compounded drug preparations, the BUD does not exceed any of the following: (CCR 1735.2[i][2][A-D])

- ☐ 2.9.2.1. The shortest expiration date or BUD of any ingredient in the sterile compounded drug preparation,
- ☐ 2.9.2.2. The chemical stability of any one ingredient in the sterile compounded drug preparation,
- ☐ 2.9.2.3. The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and
- ☐ 2.9.2.4. The BUD assigned for sterility in CCR 1751.8.

☐ 2.9.3. For sterile compounded drug preparations, extension of a BUD is supported by the following: (CCR 1735.2[i][3][A-C])

- ☐ 2.9.3.1. Method Suitability Test,
- ☐ 2.9.3.2. Container Closure Integrity Test, and
- ☐ 2.9.3.3. Stability Studies.

☐ 2.9.4. The finished drugs or compounded drug preparations tested and studied are compounded using the same identical components or ingredients,

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specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation. (CCR 1735.2[i][4])

☐ 2.9.5. Shorter dating is used if it is deemed appropriate in the professional judgment of the responsible pharmacist. (CCR 1735.2[i][5])

Yes No N/A

☐ ☐ ☐ 2.10. The pharmacist performing, or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug preparation. (CCR 1735.2[j])

☐ ☐ ☐ 2.11. Self-assessment is completed, as required, prior to compounding a drug preparation. (CCR 1735.2[k])

☐ ☐ ☐ 2.12. Packages of ingredients, both active and inactive, which lack a supplier's expiration date are subject to the following limitations: (CCR 1735.2[l])

- ☐ 2.12.1. Ingredients are not used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.
- ☐ 2.12.2. Ingredients are not used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

☐ ☐ ☐ 2.13. The Pharmacy distributes compounded human drug preparation interstate and complies with the following conditions: (BPC 4126.10[a][1-3])

- ☐ 2.13.1. The pharmacy reports all required data for the previous calendar year into the Information Sharing Network established by the National Association of Boards of Pharmacy in conjunction with the United States Food and Drug Administration (FDA).
- ☐ 2.13.2. On an annual basis, in connection with and as a condition of renewal of the pharmacy's license, the pharmacist-in-charge of the pharmacy certifies that the reporting requirements of above have been satisfied.
- ☐ 2.13.3. The pharmacy reports any adverse drug experience and product quality issue for any compounded product to the board within 12 hours after the pharmacy receives notice of the adverse drug experience or product quality issue.

☐ ☐ ☐ 2.14. Pharmacy and pharmacist-in-charge understand the Information reported by the board to the FDA directly or through the Information Sharing Network established by the National Association of Boards of Pharmacy in conjunction with the FDA to implement the Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products is not subject to public disclosure under the California Public Records Act (Chapter 1 (commencing with Section 7920.000) of Part 1 of Division 10 of Title 1 of Government Code). (BPC 4126.10[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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3. Recordkeeping for Compounded Drug Preparation (CCR 1735.3)

Yes No N/A

☐ ☐ ☐ 3.1. The pharmacy makes and retains a record for each compounded drug preparation which includes, at least, the following: (CCR 1735.3[a][1-2])

- ☐ 3.1.1. The master formula document.
- ☐ 3.1.2. A compounding log consisting of a single document containing all of the following:
- ☐ 3.1.2.1. The name and strength of the compounded drug preparation.
- ☐ 3.1.2.2. The date the drug preparation was compounded.
- ☐ 3.1.2.3. The identity of the pharmacy personnel who compounded the drug preparation.
- ☐ 3.1.2.4. The identity of the pharmacist reviewing the final drug preparation.
- ☐ 3.1.2.5. The quantity of each component used in compounding the drug preparation.
- ☐ 3.1.2.6. The manufacturer or supplier, expiration date and lot number of each component.
- ☐ 3.1.2.7. The pharmacy assigned reference or lot number for the compounded drug preparation.
- ☐ 3.1.2.8. The BUD or BUD and time of the final compounded drug preparation.
- ☐ 3.1.2.9. The final quantity or amount of drug preparation compounded.
- ☐ 3.1.2.10. Documentation of quality reviews and required post-compounding process and procedures.

☐ ☐ ☐ 3.2. The pharmacy maintains records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, components and drug products used in compounding. (CCR 1735.3[b])

☐ ☐ ☐ 3.3. Active ingredients are obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug components used to compound drug preparations are to be obtained, whenever possible, from FDA-registered suppliers. The pharmacy acquires and retains certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. (CCR 1735.3[c])

☐ ☐ ☐ 3.4. The pharmacy maintains and retains all records required in the pharmacy in a readily retrievable form for at least three years. (CCR 1735.3[d])

CORRECTIVE ACTION OR ACTION PLAN: _____

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4. Labeling of Compounded Drug Preparation (CCR 1735.4)

Yes No N/A

☐ ☐ ☐ 4.1. Each compounded drug preparation has at least the following affixed to the container on a label prior to dispensing: (CCR 1735.4[a][1-6])

- ☐ 4.1.1. Name of the compounding pharmacy and dispensing pharmacy (if different);
- ☐ 4.1.2. Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed intravenous (IV) solutions, the IV solution utilized shall be included;
- ☐ 4.1.3. Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;
- ☐ 4.1.4. The BUD for the drug preparation;
- ☐ 4.1.5. The date compounded; and
- ☐ 4.1.6. The lot number or pharmacy reference number.

☐ ☐ ☐ 4.2. Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient is labeled with the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5. (CCR 1735.4[b])

☐ ☐ ☐ 4.3. Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient also includes, on the container label or on a receipt provided to the patient, a statement the drug preparation has been compounded by the pharmacy. (CCR 1735.4[c])

☐ ☐ ☐ 4.4. Drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with the requirements of CCR 1735.4(a), (b), and (c) are labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and BUD. (CCR 1735.4[d])

☐ ☐ ☐ 4.5. All hazardous agents bear a special label which states “Chemotherapy - Dispose of Properly” or “Hazardous – Dispose of Properly.” (CCR 1735.4[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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5. Compounding Policies and Procedures (CCR 1735.5)

Yes No N/A

☐ ☐ ☐ 5.1. The pharmacy maintains written policies and procedure for compounding which establish procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation,

and other standard operating procedures related to compounding. (CCR 1735.5[a])

Yes No N/A

☐ ☐ ☐ 5.2. The policy and procedures are reviewed on an annual basis by the pharmacist-in-charge and are updated whenever changes in policies and procedures are implemented. (CCR 1735.5[b])

☐ ☐ ☐ 5.3. The policies and procedures include at least the following: (CCR 1735.5[c][1-11])

- ☐ 5.3.1. Procedures for notifying staff assigned to compounding duties of any changes in policies or procedures.
- ☐ 5.3.2. 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 ensures 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).
- ☐ 5.3.3. 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.
- ☐ 5.3.4. 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.
- ☐ 5.3.5. 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.
- ☐ 5.3.6. Documentation of the methodology and rationale or reference source used to determine appropriate BUDs for compounded drug preparations.
- ☐ 5.3.7. Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.
- ☐ 5.3.8. Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.
- ☐ 5.3.9. 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.
- ☐ 5.3.10. Policies and procedures for ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.
- ☐ 5.3.11. Policies and procedures for proper garbing when compounding with hazardous products; including when to utilize double shoe covers.

CORRECTIVE ACTION OR ACTION PLAN: _____

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6. Compounding Facilities and Equipment (CCR 1735.6)

Yes No N/A

☐ ☐ ☐ 6.1. The pharmacy maintains written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug preparations which includes records of certification of facilities or equipment, if applicable. (CCR 1735.6[a])

☐ ☐ ☐ 6.2. All equipment used to compound a drug preparation is stored, used, maintained, and cleaned in accordance with manufacturers' specifications. (CCR 1735.6[b])

☐ ☐ ☐ 6.3. All equipment used to compound a drug preparation is calibrated prior to use to ensure accuracy. (CCR 1735.6[c])

- ☐ 6.3.1. Documentation of each calibration is recorded in a form which is not alterable and is maintained and retained in the pharmacy.

☐ ☐ ☐ 6.4. When engaged in hazardous drug compounding, the pharmacy maintains written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs. (CCR 1735.6[d])

☐ ☐ ☐ 6.5. Hazardous drug compounding is completed in an externally exhausted physically separate room with the following requirements: (CCR 1735.6[e])

- ☐ 6.5.1. 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 preparations are assigned a BUD of 12 hours or less or when nonsterile products are compounded; and
- ☐ 6.5.2. 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
- ☐ 6.5.3. For sterile compounding, each BSC or CACI shall be externally exhausted.
- ☐ 6.5.3. 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,
- ☐ 6.5.4. All surfaces within the room are smooth, seamless, impervious, and non-shedding.

CORRECTIVE ACTION OR ACTION PLAN: _____

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7. Training of Compounding Staff (CCR 1735.7)

Yes No N/A

☐ ☐ ☐ 7.1. The pharmacy maintains documentation demonstrating personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating all personnel involved in compounding are trained in all aspects of policies and

procedures. This training includes, but is not limited to, support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacists and all others whose jobs are related to the compounding process. (CCR 1735.7[a])

Yes No N/A

☐ ☐ ☐ 7.2. The pharmacy has developed and maintains an ongoing 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. (CCR 1735.7[b])

☐ ☐ ☐ 7.3. Pharmacy personnel assigned to compounding duties demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation. (CCR 1735.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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8. Compounding Quality Assurance (CCR 1735.8)

Yes No N/A

☐ ☐ ☐ 8.1. The pharmacy maintains, as part of its written policies and procedures, a written quality assurance plan to monitor and ensure the integrity, potency, quality and labeled strength of compounded drug preparation. (CCR 1735.8[a])

☐ ☐ ☐ 8.2. The pharmacy's quality assurance plan includes the written procedures and standards for at least the following:

- ☐ 8.2.1. Verification, monitoring and review of the adequacy of the compounding processes as well as documentation of review of those processes by qualified pharmacy personnel. (CCR 1735.8[b])
- ☐ 8.2.2. Qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality and labeled strength, including the frequency of testing. Frequency of routine testing and analysis is done on an annual basis. (CCR 1735.8[c])
- ☐ 8.2.3. Such reports are retained by the pharmacy and collated with the compounding record and master formula document. (CCR 1735.8[c])
- ☐ 8.2.4. Scheduled action in the event any compounded drug preparation is ever discovered to be below minimum standards for integrity, potency, quality or labeled strength. (CCR 1735.8[d])
- ☐ 8.2.5. Response to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing. (CCR 1735.8[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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9. Compounding Consistent with United States Pharmacopeia – National Formulary (Business and Professions Code (BPC) 4126.8)

Yes No N/A

☐ ☐ ☐ 9.1. The compounding of drug preparation is consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance.

CORRECTIVE ACTION OR ACTION PLAN: _____

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10. Duties of a Pharmacy Issuing a Compounded Drug Recall (BPC 4126.9)

Yes No N/A

☐ ☐ ☐ 10.1. When the pharmacy issues a recall notice regarding a nonsterile compounded drug product, in addition to any other duties, all of the following take place: contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board within 12 hours of the recall notice if both of the following apply: (BPC 4126.9[a][1-2])

- ☐ 10.1.1. Use of or exposure to the recalled drug may cause serious adverse health consequences or death.
- ☐ 10.1.2. The recalled drug was dispensed, or is intended for use, in this state.

☐ ☐ ☐ 10.2. A recall notice issued pursuant to subdivision (a) is made as follows: (BPC 4126.9[b][1-3])

- ☐ 10.2.1. If the recalled drug was dispensed directly to the patient, the notice is made to the patient.
- ☐ 10.2.2. If the recalled drug was dispensed directly to the prescriber, the notice is made to the prescriber, who shall ensure the patient is notified.
- ☐ 10.2.3. If the recalled drug was dispensed directly to a pharmacy, the notice is made to the pharmacy, which shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber ensures the patient is notified.

☐ ☐ ☐ 10.3. If the pharmacy has been advised that a patient has been harmed by using a nonsterile compounded product potentially attributable to the pharmacy, the pharmacy reports the event to MedWatch within 72 hours of the pharmacy being advised. (BPC 4126.9[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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COMPOUNDING STERILE DRUGS

Does the pharmacy compound sterile drug preparations? (BPC 4127)

☐ **Yes** ☐ **No**

If yes, complete Sections 11 through 27.
If no, proceed to the certification on page 30.

FOR PHARMACIES THAT COMPOUND STERILE DRUG preparations:

11. Compounding Drug for Other Pharmacy for Parenteral Therapy

Yes No N/A

☐ ☐ ☐ 11.1. Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report that contractual arrangement to the board. (BPC 4123)

- ☐ 11.1.1. The contractual arrangement is reported to the board within 30 days of commencing that compounding.

CORRECTIVE ACTION OR ACTION PLAN: _____

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12. Sterile Compounding; Compounding Area (CCR 1751)

Yes No N/A

☐ ☐ ☐ 12.1. The pharmacy conforms 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. (CCR 1751[a])

☐ ☐ ☐ 12.2. The pharmacy has a compounding area designated for the preparation of sterile drug preparations in a restricted location where traffic has no impact on the performance of the Primary Engineering Control(s) (PEC). (CCR 1751[b])

- ☐ 12.2.1. The cleanroom, including the walls, ceilings, and floors, are constructed in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.
- ☐ 12.2.2. The pharmacy is ventilated in a manner in accordance with Section 505.7 of Title 24, Part 4, Chapter 5 of the California Code of Regulations.
- ☐ 12.2.3. The environments within the pharmacy meet at least the following standards: (CCR 1751[b])
- ☐ 12.2.3.1. Each ISO environment is certified at least every six months by a qualified technician in accordance with CCR 1751.4.
  - ☐ 12.2.3.1.1. Certification records must be retained in the pharmacy.

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☐ 12.2.3.2. Items related to the compounding of sterile drug preparations within the compounding area are stored in such a way as to maintain the integrity of an aseptic environment.

☐ 12.2.3.3. A sink is included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains are not 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.

☐ 12.2.3.4. There is 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 is in place to ensure continuity of available compounded drug preparations in the event of a power outage.

CORRECTIVE ACTION OR ACTION PLAN: _____

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13. Sterile Compounding; Compounding Area (24 CCR 1250.4, 505.12 and 505.12.1)

TITLE 24, PART 2, BUILDING CODE, CHAPTER 12, and PART 4, MECHANICAL CODE, CALIFORNIA CODE OF REGULATIONS

Yes No N/A

☐ ☐ ☐ 13.1. The pharmacy has a designated area for the preparation of sterile products for dispensing which meets at least the following: (24 CCR 1250.4)

☐ 13.1.1. In accordance with Federal Standard 209(b), Clean Room and Work Station Requirements, Controlled Environment, as approved by the Commission, Federal Supply Service, General Services Administration meet standards for class 100 HEPA (high efficiency particulate air) filtered air such as laminar air flow hood or clean room. (24 CCR 1250.4[1])

☐ 13.1.2. Has non-porous and cleanable surfaces, walls, floors, ceilings and floor coverings. (24 CCR 1250.4[2])

☐ 13.1.3. The pharmacy is arranged in such a manner that the laminar-flow hood (PEC) is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral preparations. There is sufficient space, well separated from the laminar-flow hood area, for the storage of bulk materials, equipment, and waste materials. (24 CCR 1250.4[3])

☐ 13.1.4. A sink with hot and cold running water is within the parenteral preparation compounding area or adjacent to it. (24 CCR 1250.4[4])

☐ 13.1.5. The pharmacy compounding sterile injectable preparations from one or more nonsterile ingredients, compounds the preparations in one of the following environments: (24 CCR 1250.4[5])

☐ 13.1.5.1. An ISO Class 5 laminar airflow hood within an ISO Class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.

☐ 13.1.5.2. An ISO Class 5 cleanroom.

☐ 13.1.5.3. A barrier isolator that provides an ISO Class 5 environment for compounding.

Yes No N/A

☐ ☐ ☐ 13.2. The pharmacy has a designated area for the compounding of sterile preparations for dispensing which shall: (24 CCR 505.12)

☐ 13.2.1. Be ventilated in a manner not interfering with laminar air flow.

☐ ☐ ☐ 13.3. Pharmacies preparing parenteral cytotoxic agents, all compounding is conducted within a certified Class II Type A or Class II Type B vertical laminar air flow hood with bag in-bag out design. The pharmacy ensures that contaminated air plenums under positive air pressure are leak tight. (24 CCR 505.12.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

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14. Sterile Compounding Recordkeeping Requirements. (CCR 1751.1)

Yes No N/A

☐ ☐ ☐ 14.1. In addition to the records required by CCR 1735.3, the pharmacy maintains at least the following records, which are readily retrievable within the pharmacy: (CCR 1751.1[a][1-11])

- ☐ 14.1.1. Documents evidencing training and competency evaluations of employees in sterile drug preparation policies and procedures.
- ☐ 14.1.2. Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.
- ☐ 14.1.3. 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.
- ☐ 14.1.4. Results of viable air and surface sampling.
- ☐ 14.1.5. Biannual video of smoke studies in all ISO Class 5 certified spaces.
- ☐ 14.1.6. Documents indicating daily documentation of room, refrigerator, and freezer temperatures appropriate for sterile compounded drug preparations consistent with the temperatures listed in CCR 1735.1 for:
  - ☐ 14.1.6.1. Controlled room temperature.
  - ☐ 14.1.6.2. Controlled cold temperature.
  - ☐ 14.1.6.3. Controlled freezer temperature.
- ☐ 14.1.7. Certification(s) of the sterile compounding environment(s).
- ☐ 14.1.8. 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.
- ☐ 14.1.9. Other facility quality control records specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).

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☐ 14.1.10. Logs or other documentation of inspections for expired or recalled chemicals, bulk drug substances, drug products, or other ingredients.

☐ 14.1.11. Preparation records including the master formula document, the preparation compounding log, and records of end-product evaluation testing and results.

Yes No N/A

☐ ☐ ☐ 14.2. The pharmacy compounds for future use pursuant to CCR 1735.2 and, in addition to those records required by CCR 1735.3, makes and keeps 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. (CCR 1751.1[b])

☐ ☐ ☐ 14.3. The pharmacy maintains and retains 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 are maintained as specified by Business and Professions Code section 4070 subsection (c). (CCR 1751.1[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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15. Sterile Labeling Requirements (CCR 1751.2)

Yes No N/A

☐ ☐ ☐ 15.1 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, the pharmacy labels each compounded sterile drug preparation with at least the following information: (CCR 1751.2[a-c])

☐ 15.1.1. The telephone number of the pharmacy.

☐ 15.1.2. Instructions for storage, handling, and administration.

☐ 15.1.3. All hazardous agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "Hazardous – Dispose of Properly."

CORRECTIVE ACTION OR ACTION PLAN: _____

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16. Sterile Policies and Procedures (CCR 1751.3)

Yes No N/A

☐ ☐ ☐ 16.1 The pharmacy maintains written policies and procedures for compounding and understands any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. (CCR 1751.3[a])

☐ ☐ ☐ 16.2 In addition to the elements required by CCR 1735.5 (section 5, above), there are written policies and procedures regarding at least the following: (CCR 1751.3[a][1-24])

- ☐ 16.2.1. 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.
- ☐ 16.2.2. Airflow considerations and pressure differential monitoring.
- ☐ 16.2.3. An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.
- ☐ 16.2.4. Cleaning and maintenance of ISO environments and segregated compounding areas.
- ☐ 16.2.5. Compounded sterile drug preparation stability and beyond use dating.
- ☐ 16.2.6. Compounding, filling, and labeling of sterile drug preparations.
- ☐ 16.2.7. Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in CCR 1751.4.
- ☐ 16.2.8. Depyrogenation of glassware (if applicable)
- ☐ 16.2.9. Facility management including certification and maintenance of controlled environments and related equipment.
- ☐ 16.2.10. For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.
- ☐ 16.2.11. Hand hygiene and garbing.
- ☐ 16.2.12. Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.
- ☐ 16.2.13. Methods by which the supervising pharmacist will fulfill their responsibility to ensure the quality of compounded drug preparations.
- ☐ 16.2.14. Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments which 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.
- ☐ 16.2.15. Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.
- ☐ 16.2.16. 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.

- ☐ 16.2.17. 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.
- ☐ 16.2.18. Proper use of equipment and supplies.
- ☐ 16.2.19. Quality assurance program compliant with CCR 1711, 1735.8, and 1751.7.
- ☐ 16.2.20. Record keeping requirements.
- ☐ 16.2.21. Temperature monitoring in compounding and controlled storage areas.
- ☐ 16.2.22. The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.
- ☐ 16.2.23. Use of automated compounding devices (if applicable).
- ☐ 16.2.24. Visual inspection and other final quality checks of sterile drug preparations.

Yes No N/A

☐ ☐ ☐ 16.3. For lot compounding, the pharmacy maintains written policies and procedures that include at least the following: (CCR 1751.3[b][1-3])

- ☐ 16.3.1. Use of master formula documents and compounding logs.
- ☐ 16.3.2. Appropriate documentation.
- ☐ 16.3.3. Appropriate sterility and potency testing.

☐ ☐ ☐ 16.4 For non-sterile-to-sterile batch compounding, the pharmacy maintains written policies and procedures for compounding that include at least the following. (CCR 1751.2[c][1-2])

- ☐ 16.4.1. Process validation for chosen sterilization methods.
- ☐ 16.4.2. End-product evaluation, quantitative, and qualitative testing.

☐ ☐ ☐ 16.5. All personnel involved have read the policies and procedures before compounding sterile drug preparations. All personnel involved have read all additions, revisions, and deletions to the written policies and procedures. Each review is documented by a signature and date. (CCR 1751.3[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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17. Facility & Equipment Standards for Sterile Compounding (CCR 1751.4 and 24 CCR 505.7.1)

Yes No N/A

☐ ☐ ☐ 17.1. No sterile drug preparation is 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. (CCR 1751.4[a])

Yes No N/A

☐ ☐ ☐ 17.2 During the compounding of sterile drug preparations, access to the areas designated for compounding is limited to those individuals who are properly attired. (CCR 1751.4[b])

☐ ☐ ☐ 17.3 All equipment used in the areas designated for compounding is made of a material that can be easily cleaned and disinfected. (CCR 1751.4[c])

☐ ☐ ☐ 17.4 Cleaning is done using a germicidal detergent and sterile water. A sporicidal agent is used at least monthly (CCR 1751.4[d][1-4])

- ☐ 17.4.1. All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor are cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent occurs on all ISO Class 5 surfaces, work table surfaces, carts, and counters.
- ☐ 17.4.2. Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment are cleaned at least monthly.
- ☐ 17.4.3. Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.
- ☐ 17.4.4. 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.

☐ ☐ ☐ 17.5 Disinfection, using a suitable sterile agent, occurs on all surfaces in the ISO Class 5 PEC frequently, including: (CCR 1751.4[e])

- ☐ 17.5.1. At the beginning of each shift;
- ☐ 17.5.2. At least every 30 minutes when compounding involving human staff is occurring or before each lot;
- ☐ 17.5.3. After each spill; and
- ☐ 17.5.4. When surface contamination is known or suspected.

☐ ☐ ☐ 17.6 Pharmacies preparing sterile compounded preparations are using a PEC that provides ISO Class 5 air or better air quality. (CCR 1751.4[f])

- ☐ 17.6.1. Certification and testing of primary and secondary engineering controls are 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 which would impact the device or area.
- ☐ 17.6.2. Certification is 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).
  - ☐ 17.6.2.1. Certification records are retained for at least 3 years.
- ☐ 17.6.3. Unidirectional compounding aseptic isolators or compounding aseptic containment isolators used outside of an ISO Class 7 cleanroom if the isolators are certified to meet the following criteria: (CCR 1751.4[f][1-3])

☐ 17.6.3.1. Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.

☐ 17.6.3.2. 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.

☐ 17.6.3.3. 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.

☐ 17.6.4. Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom are only 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.

Yes No N/A

☐ ☐ ☐ 17.7. Pharmacies preparing sterile hazardous agents do so in accordance with Section 505.7.1 of Title 24, Part 5, Chapter 5, of the California Code of Regulations, requiring a negative pressure PEC.

☐ 17.7.1. Additionally, each PEC used to compound hazardous agents is externally vented.

☐ 17.7.2. The negative pressure PEC is 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).

☐ 17.7.3. Any drug preparation compounded in a PEC where hazardous drugs are prepared are labeled as hazardous, regardless of whether the drug ingredients are considered hazardous. (CCR 1751.4[g])

☐ 17.7.4. During hazardous drug compounding performed in a compounding aseptic containment isolator, full hand hygiene and garbing occurs. Garbing includes 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. (CCR 1751.4[g][1])

☐ ☐ ☐ 17.8. 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 who use compounding aseptic isolators in this manner ensure appropriate garbing, which consists of donning sterile gloves over the isolator gloves immediately before non-hazardous compounding. These sterile gloves are changed by each individual whenever continuous compounding is ceased and before compounding starts again. (CCR 1751.4[h])

Yes No N/A

☐ ☐ ☐ 17.9. Compounding aseptic isolators and compounding aseptic containment isolators used in the compounding of sterile drug preparations use non-turbulent unidirectional air flow patterns. A smoke patterned test is used to determine air flow patterns. (CCR 1751.4[i])

☐ ☐ ☐ 17.10. Viable surface sampling is done at least every six months for all sterile-to-sterile compounding and quarterly for all non-sterile-to-sterile compounding. (CCR 1751.4[j])

- ☐ 17.10.1. Viable air sampling is done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and is done at least once every six months.
- ☐ 17.10.2. Viable surface and viable air sampling are performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling.
- ☐ 17.10.3. Viable air sampling is performed under dynamic conditions which simulate actual production.
- ☐ 17.10.4. Viable surface sampling is performed under dynamic conditions of actual compounding.
- ☐ 17.10.5. When the environmental monitoring action levels are exceeded, the pharmacy identifies the CFUs at least to the genus level in addition to conducting an investigation pursuant to its policies and procedures. Remediation includes, at minimum, an immediate investigation of cleaning and compounding operations and facility management.

☐ ☐ ☐ 17.11. The sterile compounding area in the pharmacy has 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. (CCR 1751.4[k])

CORRECTIVE ACTION OR ACTION PLAN: _____

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18. Sterile Compounding Attire (CCR 1751.5)

Yes No N/A

☐ ☐ ☐ 18.1. When compounding sterile drug preparations, the following standards are met: (CCR 1751.5[a][1-6])

- ☐ 18.1.1. Personal protective equipment consisting of a low non-shedding coverall gown, head cover, face mask, facial hair covers (if applicable), and shoe covers are worn inside the designated area at all times. For hazardous compounding, double shoe covers are worn.
- ☐ 18.1.2. Personal protective equipment is donned and removed in an ante-area or immediately outside the segregated compounding area.

☐ 18.1.3. Personnel dons personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest.

☐ 18.1.4. Compounding personnel does not wear any wrist, hand, finger, or other visible jewelry, piercing, headphones, earbuds, or personal electronic devices.

☐ 18.1.5. Sterile gloves that have been tested for compatibility with disinfection by isopropyl alcohol are worn.

☐ 18.1.6. Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom.

☐ 18.1.7. Gloves are routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects.

☐ 18.1.8. Gloves are routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.

☐ 18.1.9. Individuals experiencing exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, nail polish, or artificial nails are excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.

Yes No N/A

☐ ☐ ☐ 18.2. When preparing hazardous agents, appropriate gowns and personal protective equipment are worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator). (CCR 1751.5[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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19. Sterile Compounding Consultation; Training of Sterile Compounding Staff. (CCR 1751.6)

Yes No N/A

☐ ☐ ☐ 19.1. Consultation is 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. (CCR 1751.6[a])

☐ ☐ ☐ 19.2. The pharmacist-in-charge ensures 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. (CCR 1751.6[b])

Yes No N/A

☐ ☐ ☐ 19.3. Records of training and demonstrated competence are available for each individual and shall be retained for three years beyond the period of employment. (CCR 1751.6[c])

☐ ☐ ☐ 19.4. The pharmacist-in-charge is responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile drug preparations. (CCR 1751.6[d])

☐ ☐ ☐ 19.5. The pharmacy complies with at least the following training requirements: (CCR 1751.6[e])

- ☐ 19.5.1. The pharmacy establishes and follows a written program of training and performance evaluation designed to ensure 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 addresses at least the following: (CCR 1751.6[e][1][A-J])
  - ☐ 19.5.1.1. Aseptic technique.
  - ☐ 19.5.1.2. Pharmaceutical calculations and terminology.
  - ☐ 19.5.1.3. Sterile preparation compounding documentation.
  - ☐ 19.5.1.4. Quality assurance procedures.
  - ☐ 19.5.1.5. Aseptic preparation procedures.
  - ☐ 19.5.1.6. Proper hand hygiene, gowning and gloving technique.
  - ☐ 19.5.1.7. General conduct in the controlled area (aseptic area practices).
  - ☐ 19.5.1.8. Cleaning, sanitizing, and maintaining of the equipment and the controlled area.
  - ☐ 19.5.1.9. Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients.
  - ☐ 19.5.1.10. Container, equipment, and closure system selection.
- ☐ 19.5.2. Each person engaged in sterile compounding has successfully completed 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. (CCR 1751.6[e][2])
  - ☐ 19.5.2.1. Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, demonstrates the skills needed to ensure the sterility of compounded drug preparations.
  - ☐ 19.5.2.2. Evaluation includes written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures.
  - ☐ 19.5.2.3. Each person's proficiency and continuing training needs are reassessed at least every 12 months.
  - ☐ 19.5.2.3. Results of these assessments are documented and retained in the pharmacy for three years.

CORRECTIVE ACTION OR ACTION PLAN: _____

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20. Sterile Compounding Quality Assurance and Process Validation (CCR 1751.7)

Yes No N/A

☐ ☐ ☐ 20.1. There is a written, documented, ongoing quality assurance program maintained by the pharmacy that monitors personnel performance, equipment, and facilities, and the pharmacist-in-charge assures the end-product meets the required specifications by periodic sampling. (CCR 1751.7[a])

- ☐ 20.1.1. The quality assurance program shall include at least the following: (CCR 1751.7[a][1-3])
  - ☐ 20.1.1.1. Procedures for cleaning and sanitization of the sterile preparation area.
  - ☐ 20.1.1.2. Actions to be taken in the event of a drug recall.
  - ☐ 20.1.1.3. Documentation justifying the chosen BUDs for compounded sterile drug preparations.

☐ ☐ ☐ 20.2. The pharmacy and each individual involved in the compounding of sterile drug preparations successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. (CCR 1751.7[b][1])

- ☐ 20.2.1. Each individual's competency is 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. (CCR 1751.7[b][2])
- ☐ 20.2.2. The pharmacy's validation process on aseptic technique and aseptic area practices is to be revalidated whenever: (CCR 1751.7[b][3][A-B])
  - ☐ 20.2.2.1. The quality assurance program yields an unacceptable result.
  - ☐ 20.2.2.2. 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 affecting airflow or traffic patterns, or when improper aseptic techniques are observed.
- ☐ 20.2.3. The pharmacy must document the validation and revalidation process (CCR 1751.7[b][4]).

☐ ☐ ☐ 20.3 All sterile compounding personnel have successfully completed 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 has successfully completed 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. (CCR 1751.7[c])

☐ ☐ ☐ 20.4 Re-evaluation of garbing and gloving competency occurs 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. (CCR 1751.7[d])

PIC Initials

Yes No N/A

☐ ☐ ☐ 20.5 Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients are subject to documented end product testing for sterility and pyrogens and are quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing is performed per USP chapter 71 and pyrogen testing confirms acceptable levels of pyrogen per USP chapter 85 limits before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing applies regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients which were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparation. (CCR 1751.7[e][1])

- ☐ 20.5.1. The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens: (CCR 1751.7[e][2][A-B)
  - ☐ 20.5.1.1. 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.
  - ☐ 20.5.1.2. Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.

CORRECTIVE ACTION OR ACTION PLAN: _____

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21. Beyond Use Dating for Sterile Compounded Drug Preparations (CCR 1751.8)

Yes No N/A

☐ ☐ ☐ 21.1. Every sterile compounded drug preparation is given and labeled with a BUD in compliance with CCR 1735.2 and does not exceed the shortest expiration date or BUD of any ingredient in the 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, in the absence of passing a sterility test in accordance with standards for sterility testing found in the current version of Chapter 797 of the United States Pharmacopeia-National Formulary would justify an extended BUD, conforms to the following limitations:

☐ ☐ ☐ 21.2. The BUD states 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: (CCR 1751.8[a])

☐ 21.2.1. 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 CCR 1751.4(f)(1)-(3), using only sterile ingredients, products, components, and devices; and

☐ 21.2.2. 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

☐ 21.2.3. 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.

Yes No N/A

☐ ☐ ☐ 21.3. The BUD states 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: (CCR 1751.8[b])

☐ 21.3.1. 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 CCR 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

☐ 21.3.2. The compounding process involves complex aseptic manipulations other than the single-volume transfer; and

☐ 21.3.3. The compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing.

☐ ☐ ☐ 21.4. The BUD states 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: (CCR 1751.8[c])

☐ 21.4.1. 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 CCR 1751.4(f)(1)-(3).

☐ ☐ ☐ 21.5. The BUD states 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: (CCR 1751.8[d])

☐ 21.5.1. 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

☐ 21.5.2. 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

☐ 21.5.3. 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.

Yes No N/A

☐ ☐ ☐ 21.6. For any sterile compounded drug preparation which was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements of CCR 1751.8, subdivisions (a) through (d), (sections 21.2-21.5, above), the sterile compounded drug preparation is to be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process. (CCR 1751.8[e])

☐ 21.6.1. 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 BUD and time.

☐ 21.6.2. 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.

☐ 21.6.3. "Immediate use" preparations are only compounded 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.

☐ 21.6.4. Any immediate use 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.

Yes No N/A

☐ ☐ ☐ 21.7. The BUD for any compounded allergen extracts is the earliest manufacturer expiration date of the individual allergen extracts. (CCR 1751.8[f])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

22. Single-Dose and Multi-Dose Containers; Limitations on Use (CCR 1751.9)

Yes No N/A

☐ ☐ ☐ 22.1. Single-dose ampules are for immediate use only, and once opened are not stored for any time period. (CCR 1751.9[a])

☐ ☐ ☐ 22.2. 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, is used in its entirety or its remaining contents are to be labeled with a BUD and discarded within the following time limit, depending on the environment: (CCR 1751.9[b])

- ☐ 22.2.1. When needle-punctured in an environment with air quality worse than ISO Class 5, within one (1) hour.
- ☐ 22.2.2. When needle-punctured in an environment with ISO Class 5 or better air quality, within six (6) hours. A container remains within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.
- ☐ 22.2.3. If the puncture time is not noted on the container, the container is immediately discarded.

☐ ☐ ☐ 22.3. Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications is used in its entirety or its remaining contents are to be labeled with a BUD and discarded within twenty-eight (28) days from initial opening or puncture. (CCR 1751.9[c])

- ☐ 22.3.1. Any multi-dose container not stored according to the manufacturer's specifications is discarded immediately upon identification of such storage circumstance.
- ☐ 22.3.2. If any open container is not labeled with a BUD or the BUD is not correct, the container is immediately be discarded.

CORRECTIVE ACTION OR ACTION PLAN: _____

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23. Sterile Compounding Reference Materials (CCR 1751.10)

Yes No N/A

☐ ☐ ☐ 23.1. The pharmacy has current and appropriate reference materials regarding the compounding of sterile drug preparations located in or immediately available to the pharmacy. (CCR 1751.10)

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials _____

24. Sterile Compounding License Renewal (BPC 4127.1, 4127.15, 4127.2)

A license to compound sterile drug preparation must meet the following conditions prior to renewal: (BPC 4127.1, 4127.15, 4127.2)

Yes No N/A

☐ ☐ ☐ 24.1. The pharmacy has been inspected by the board and is in compliance with applicable laws and regulations.

☐ ☐ ☐ 24.2. The board is provided a current copy of the pharmacy's policies and procedures for sterile compounding.
Date provided: _____

☐ ☐ ☐ 24.3. The board is provided with copies of all inspection reports conducted of the pharmacy's premises in the prior 12 months documenting the pharmacy's operation.
Date provided: _____

☐ ☐ ☐ 24.4. The board is provided with copies of any reports from a private accrediting agency conducted in the prior 12 months documenting the pharmacy's operation.
Date provided: _____

☐ ☐ ☐ 24.5. The board is provided a list of all sterile medications compounded by the pharmacy since the last license renewal.
Date provided: _____

☐ ☐ ☐ 24.6. A nonresident pharmacy has reimbursed the board for all actual and necessary costs incurred by the board in conducting an inspection of the pharmacy at least once annually. (BPC 4127.2[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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25. Hospital Satellite Compounding Pharmacy (BPC 4127.15)

Yes No N/A

☐ ☐ ☐ 25.1. A hospital satellite compounding pharmacy compounds sterile drug products for administration only to registered hospital patients who are on the premises of the same physical plant in which the hospital satellite compounding pharmacy is located. (BPC 4127.15[a][1])

☐ ☐ ☐ 25.2. The services provided shall be directly related to the services or treatment plan administered in the physical plant. (BPC 4127.15[a][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

26. Nonresident Pharmacy (BPC 4127.2)

Yes No N/A

☐ ☐ ☐ 26.1. Pharmacy notifies the board within 10 days of the suspension of any accreditation held by the pharmacy. (BPC 4127.2[e][2])

☐ ☐ ☐ 26.2. Pharmacy provides to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded that have been shipped into, or dispensed in, California. (BPC 4127.2[e][3])

☐ ☐ ☐ 26.3. Pharmacy advises the board of any complaint it receives from a provider, pharmacy, or patient in California. (BPC 4127.2[e][4])

CORRECTIVE ACTION OR ACTION PLAN: _____

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27. Duties of a Pharmacy Issuing a Sterile Compounded Drug Recall (BPC 4127.8)

Yes No N/A

☐ ☐ ☐ 27.1. The pharmacy contacts the recipient pharmacy, prescriber, or patient of a recalled drug and the board as soon as possible within 12 hours of the recall notice if both (1) the use of or exposure to the recalled drug preparations may cause serious adverse health consequences or death; and (2) the recalled drug was dispensed or is intended for use in California. (BPC 4127.8[a])

☐ ☐ ☐ 27.2. A recall notice is made to the patient if the recalled drug was dispensed directly to the patient. (BPC 4127.8[b][1])

☐ ☐ ☐ 27.3. A recall notice is made to the prescriber if the recalled drug was dispensed directly to the prescriber. (BPC 4127.8[b][2])

☐ ☐ ☐ 27.4. A recall notice is made to the recipient pharmacy who shall notify the prescriber or patient if the recalled drug was dispensed thereafter. (BPC 4127.8[b][3])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected by _____ (insert date). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature _____ _____
(Pharmacist-in-Charge) Date

ACKNOWLEDGEMENT BY OWNER OR HOSPITAL ADMINISTRATOR:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment in the timeframe identified in the Pharmacist-in-Charge Certification above could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ _____
Date

_____
PIC Initials