Alliance for Pharmacy Compounding

Compounding the Joy of Living

USP 797 Standards vs. Proposed California Board of Pharmacy Rules

New USP 797	California Proposed
<u>Compounding</u> ● Process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance to create a sterile preparation. ● Docking and activation in accordance with manufacturer's instructions for immediate administration to an individual patient is NOT considered compounding. Docking for future activation and administration is considered compounding. ● Immediate use CSP (direct and immediate administration) - Must use aseptic techniques, processes and procedures are followed and written SOPs are in place. Personnel are trained and demonstrate competency in aseptic processes. Performed in accordance with evidence-based information for physical and chemical compatibility of the drug. Involves no more than 3 different sterile products. Unused starting components from single-dose containers must be discarded after preparation is complete. Administration begins within 4 hours or discarded. No labeling requirement when administered by the preparer. Not subject to requirements for category 1, category 2, or category 3 CSPs.	<u>Compounding</u> ● Compounded sterile preparations (CSPs) for direct and immediate administration only done in limited situations where failure to administer could result in loss of life or intense suffering. Quantity produced may only be the amount to meet immediate need. Documentation should include identification of CSP, compounded date, time, number of units, patient's name, patient's unique identifier and cause of immediate need.

Equipment, Supplies and Components ● Component selection: conventionally manufactured sterile products should be used when available and appropriate, evaluated for suitability for use in sterile drug preparation. Components labeled with “not for pharmaceutical use”, “not for injectable use”, “not for human use”, or an equivalent statement must not be used to compound for these purposes. ● Active pharmaceutical Ingredients (API): Must comply with criteria in the USP - NF monograph, must have a CoA, must be manufactured by an FDA-registered facility	Equipment, Supplies and Components ● Any component used to compound a CSP should be used and stored in accordance with all federal laws and regulations and industry standards including the manufacturers’ specifications and requirements. ● All components used to compound a CSP should be manufactured by an FDA-registered facility and suitable for use in sterile pharmaceuticals. A certificate of analysis (CoA) which includes the compendial name, the grade of the material, and the applicable compendial designations on the CoA must be received and evaluated prior to use. ● If bulk drug substance or API is used to compound a CSP, it shall comply with a USP drug monograph, be the active substance of an FDA approved drug, or be listed in CFR List of Bulk Drug Substances that can be used to compound drug products; unless authorized by a public health official in an emergency use situation for a patient specific compounded sterile preparation.
Labeling ● Label - on immediate container ● Assigned internal identification number, Active ingredient(s) and amount, activity(ies), or concentrations, storage conditions if other than controlled room temperature, BUD, dosage form, total amount or volume if not obvious, SDV (single dose vial) or MDV (multiple dose vial). ● Labeling - Routes of administration, special handling instructions, warning statements, facility name and contact information	Labeling ● CSP label should include: route of intended administration, admixed CSP, the solution utilized, instruction for administration. Admixed CSP solutions - rate of infusion, range of rates of infusion, duration when the entire CSP should be administered. Name of compounding and dispensing facility (if different). Any CSP dispense to patient or readied for dispensing to a patient should include on the label the information required by Business and Professions Code section 4076 and section 1707.5
Documentation ● Personnel training, competency assessments, and qualification records including corrective actions for any failures. Certification reports,	Documentation ● Must be maintained in a readily retrievable form, for at least three years from the date the record was created or relied upon. IF only

including corrective actions for any failures. Environmental air and surface monitoring procedures and results. Equipment records (calibration, verification, maintenance), receipt of components, SOPs, MFRs, and CR, release testing records, Information related to complaints and adverse events. Results of investigation and corrective actions.	recorded and stored electronically, on magnetic media or any computerized form, the record must be maintained as specified by Business and Professions Code section 4070. Records should be created and maintained in a manner to provide an audit trail for revisions and updates of each record document. Prior versions of each record must be maintained in a readily retrievable format and include changes to the document, identification of individual who made the change, and the date of each change.