

BOARD OF PHARMACY

855-045-0220

Personnel

- (1) Personnel who prepare compounded pharmaceuticals, both sterile and non-sterile, shall be provided with appropriate training before they begin to prepare such products including for CSPs, training in the theoretical principles and practical skills of aseptic manipulations.
- (2) The pharmacist in charge (PIC) shall establish pharmacy Policies and Procedures that contain protocols in accordance with the guidelines in USP 797, for the initial training and testing of all personnel and for annual retesting in aseptic manipulative skills for those personnel involved in low and medium risk compounding.
- (3) Personnel involved in high-risk compounding must be retested in aseptic manipulative skills at least semi-annually.
- (4) The PIC shall ensure that training protocols are followed and records are kept for the training of all new personnel and for all continuing education and periodic testing that is completed.
- (5) The PIC is responsible for the procedures and the overall operation of all activities within the pharmacy and must:
 - (a) Ensure all pharmacy personnel involved in preparing compounded products are trained and have demonstrated skills commensurate with the complexity of the procedures they are performing;
 - (b) Establish a procedure for verification by a pharmacist of the preparation of each completed compounded product. This verification shall be accomplished by a review of each compounded product that includes but is not limited to:
 - (A) Ensuring that the drug, dose and dosage form ordered are appropriate for the patient;
 - (B) Verifying that the correct drugs and components were selected;
 - (C) Confirming that the calculation and quantity of each drug and component is correct;
 - (D) Verifying the label is correct and where appropriate contains all the information specified in OAR 855-041-0065 and these rules.
 - (c) Document verification by the pharmacist responsible for the review.

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Sterile Parenteral Products

- (1) In addition to complying with all the other rules in this chapter of rules that are appropriate to their practice setting, pharmacists compounding sterile parenteral products must comply with the following specific rules.
 - (a) Establish, maintain and enforce written policies and procedures associated with the pharmacy's preparation and dispensing of parenteral products. Policies and procedures shall be available for inspection at the pharmacy. These policies and procedures shall include all requirements of OAR 855-045-0230 as appropriate to the practice setting and:
 - (A) Requirements for compounding, labeling and storage of the products;
 - (B) Requirements for administration of parenteral therapy;

- (C) Requirements for storage and maintenance of equipment and supplies.
- (b) Labeling: In addition to regular labeling requirements, the label shall include:
 - (A) Rate of infusion, as appropriate;
 - (B) Beyond Use Date;
 - (C) Storage requirements or special conditions, if applicable;
 - (D) Name, quantity and concentration of all ingredients contained in the products, including primary solution;
 - (E) Initials of the pharmacist who verified the accuracy of the completed product.
- (c) Patient Care Services: Counseling shall be available to the patient or patient's agent concerning proper use of parenterals and related supplies furnished by the pharmacy.
- (2) In addition to complying with all the requirements in section (1) of this rule, licensed pharmacy personnel preparing parenteral admixtures as defined in OAR 855-045-0210 may:
 - (a) Prepare multiple source commercially available premixed parenteral admixtures;
 - (b) Prepare single source premix parenteral admixtures if the individual components of the premixed parenteral solution are commercially available;
 - (c) Reassign a parenteral admixture to another patient if the admixture does not exceed the documented BUD for that admixture, and the parenteral admixture that was prepared and dispensed for a patient specific order, and has been stored at all times under the control of a person trained and knowledgeable in the storage and administration of drugs;
 - (d) In the case of a patient specific parenteral admixture, the pharmacist does not need to comply with the worksheet and log requirements in these rules provided that a quality assurance process is in place to address drug recalls, and appropriate safeguards are in place.

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