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NON-STERILE COMPOUNDING

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CHAPTER 13

NON-STERILE COMPOUNDING

Section 1. These regulations are promulgated as authorized by the Act.

Section 2. Definitions.

(a) "Active Ingredient" means an ingredient added to a compounded prescription product that provides the therapeutic effect desired from the compounded prescription product. This does not include "inert" ingredients.

(b) "Beyond-use Date (BUD)" means a date after which a compounded product should not be used.

(c) "Component" means any ingredient used in the compounding of a drug product, including those ingredients that may not appear in the labeling of such product.

(d) "Compounding" means and includes the preparation, mixing, or assembling of a drug or device, and the packaging and labeling incident thereto for sale or dispensing:

(i) as the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of his/her professional practice.

(ii) for the purpose of research, teaching, or chemical analysis, or

(iii) in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

However, "compounding" does not include mixing or reconstituting of non-sterile products performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

(e) "Manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of the substance(s) or labeling or re-labeling of its container, and the promotion and marketing of such drugs or devices. Manufacturing also includes any preparation of a drug or device that is sold for resale by pharmacies, practitioners, or other persons.

(f) "Master Compounding Record" means an established record of all compounded products from the time of initial compounding that can be followed each time that compound is prepared in the future.

(g) "Stability" means the extent to which a compounded product retains, within specified limits and throughout its period of both storage and use, the same properties and characteristics it possessed at the time of preparation.

Section 3. General Provisions.

(a) Based on the existence of a pharmacist/patient/practitioner relationship and the presentation of a valid prescription, or in anticipation of prescription medication orders based on routine, regularly observed prescribing patterns, pharmacists may compound, for an individual patient, medications or dosage forms that are not commercially available in the marketplace.

(b) Pharmacists shall, when procuring active ingredients for compounding, obtain a Certificate of Analysis (COA) for each lot number procured, and shall retain each COA for a period of not less than two (2) years from the date the container is emptied. COAs shall be available for review by Board inspectors. Each COA must be issued by a firm located in the United States. If one is not available from the vendor, the pharmacist shall procure one from a laboratory located in the United States. COAs are not required if the active ingredient utilized is designated USP or NF.

(i) If the product is not designated as USP or NF, then the following minimum information is required on the COA:

- (A) Product name;
- (B) Lot number;
- (C) Expiration date; and
- (D) Assay.

(c) Pharmacists may compound drugs prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely within an established pharmacist/practitioner relationship, and provided that they maintain the prescriptions on file for all such products compounded at the pharmacy as required by the Board, but not under other circumstances.

(d) Pharmacists shall not offer compounded medications to other pharmacies or licensed entities for resale; except pharmacists may offer for sale compounded medications to practitioners or institutional pharmacies for administration to patients in the practitioner's office or in the institutional facility, provided that the pharmacy does not violate Chapter 8. Compounding pharmacies/pharmacists may advertise or otherwise promote the fact that they provide prescription compounding services; however, they shall not solicit business by distributing unsolicited sampling to practitioners (e.g., like a manufacturer).

(e) All compounded products, which include as an ingredient a cytotoxic drug, shall be prepared in a Class II biological safety cabinet.

Section 4. Organization and Personnel.

(a) The pharmacist has the responsibility and authority to inspect and approve or reject all components, drug product containers, closures, in-process materials, and labeling; and the authority to prepare and review all compounding records to assure that no errors have occurred in the compounding process. The pharmacist is also responsible for the proper maintenance, cleanliness, and use of all equipment used in prescription compounding practice.

(b) All pharmacists who engage in drug compounding shall be competent and proficient in compounding and shall maintain that proficiency through current awareness and training. Competency and proficiency in the art of compounding for all pharmacists shall be evaluated, documented, and maintained in the files of the pharmacy by the Pharmacist-in-Charge (PIC). Every pharmacist who engages in drug compounding must be aware of and familiar with all details of the good compounding practices.

(c) Personnel engaged in the compounding shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons, gowns, hand or arm covering, or masks shall be worn as necessary to protect personnel from chemical exposure and medication or chemical contamination.

Section 5. Drug Compounding Facilities.

(a) Pharmacies engaging in compounding shall have a specifically designated and adequate area (space) for the orderly compounding of prescriptions that is maintained in a good state of repair and for the placement of materials and equipment. Sterile compounding shall be performed in a separate area in compliance with Chapter 17.

(b) To maintain stability, bulk medications and other chemicals or materials used in the compounding of medications must be stored in adequately labeled containers in a clean, dry, and temperature-controlled area or, if required, under proper refrigeration. The refrigerator shall provide a storage temperature of 36 to 46 degrees Fahrenheit (2 to 8 degrees Centigrade). If a freezer compartment is utilized, it must maintain a temperature of -13 to +14 degrees Fahrenheit (-25 to -10 degrees Centigrade).

(c) Adequate lighting and ventilation shall be provided in all drug compounding areas. Potable water for drinking and washing shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product. Adequate washing facilities, easily accessible to the compounding area(s) of the pharmacy, shall be provided. These facilities shall include, but not be limited to, hot and cold water, soap or detergent, and air-driers or single-use towels.

(d) The area(s) used for compounding shall be maintained in a clean and sanitary condition.

(e) If sterile products are being compounded, the pharmacist shall follow Chapter 17 of this regulation.

(f) If drug products with special precautions to prevent contamination, such as penicillin, are involved in a compounding procedure, appropriate measures, including either the dedication of equipment or meticulous cleaning of contaminated equipment prior to its use for the preparation of other drugs, must be utilized in order to prevent cross-contamination.

Section 6. Equipment.

(a) Equipment and utensils used for compounding shall be of appropriate design and capacity, and shall be stored in a manner to protect from contamination. In addition, all equipment and utensils shall be cleaned prior to use to prevent contamination that would alter the safety or quality of the drug product beyond that desired.

(b) Automatic, mechanical, electronic, or other equipment used in compounding shall be routinely inspected, calibrated, or checked according to manufacturer's recommendations to ensure proper performance.

(c) It shall be the responsibility of the PIC to ensure that drug product containers, components, closures, and bagged or boxed components of drug product containers and closures used in compounding shall be handled and stored in a manner to prevent contamination and to permit unhindered inspection and cleaning of the work area.

Section 7. Compounding Controls.

(a) A Master Compounding Record shall be established for each newly compounded item and followed thereafter to monitor the output and to validate the performance of those compounding processes. The Master Compounding Record shall contain:

- (i) Official compound name, strength, and dosage form,
- (ii) Calculations required to complete the compound,
- (iii) Ingredient(s) description and amounts,
- (iv) Compatibility and stability information (references when available)
- (v) Equipment required to prepare the compound,
- (vi) Mixing instructions,
- (vii) Any other factors pertinent to the compound preparation,
- (viii) A sample label meeting all legal requirements stated in Chapter 2,
- (ix) The generic name, quantity and/or concentration of every active ingredient contained within, and
- (x) An assigned BUD as applicable.

(b) Components for compounding shall be accurately weighed, measured, or subdivided as appropriate. If a component is transferred from the original container to a new container, the new container shall be labeled with the same information as the original container and the date of transfer.

(c) Written control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug product. Such control procedures shall include, but are not limited to, the following (where appropriate):

- (i) Capsule weight variation;
- (ii) Adequacy of mixing to insure uniformity and homogeneity; and
- (iii) Clarity, completeness, or pH of solutions.

(d) At the time of dispensing to the patient, the pharmacist shall advise the patient on the proper storage, use, and anticipated shelf life of the compounded prescription product.

Section 8. Labeling Control of Excess or Bulk Compounded Products.

The pharmacist shall label any excess or bulk compounded product to reference it to the formula used and the assigned control number and estimated BUD based on the pharmacist's

professional judgment, appropriate testing or published data. The product shall be stored appropriately.

Section 9. Records and Reports.

(a) Records required to be maintained in compliance with this Chapter shall be retained for a minimum period of two (2) years from the date of last activity and be available for inspection by the Board.

(b) For each drug product compounded in excess or bulk quantities, a log book, in addition to those requirements listed in this Chapter, shall be prepared containing the following information:

(i) Name of the product;

(ii) List of ingredients and quantities used, including manufacturer, lot number, and expiration dates;

(iii) Lot number assigned by a pharmacist;

(iv) Beyond use date assigned, as described in this Chapter;

(v) Date of preparation;

(vi) Initials of compounding pharmacist, or pharmacy technician;

(vii) Initials of supervising pharmacist, if prepared by a pharmacy technician;

and

(viii) Quantity prepared.