

TITLE 30: PROFESSIONS AND OCCUPATIONS

PART 3001: MISSISSIPPI PHARMACY PRACTICE REGULATIONS

**ARTICLE XXXI COMPOUNDING GUIDELINES**

Every compounding facility under the jurisdiction of the MS Board of Pharmacy shall comply with USP 797 and 795 relating to the compounding of pharmaceuticals.

1. GENERAL PROVISIONS

- A. Pharmacists engaged in the compounding of drugs shall operate in conformance with applicable law and regulations regarding the practice of pharmacy.
- B. 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 that are not commercially available in the marketplace. No compounding and manufacturing shall take place at the same location.
- C. A Pharmacist may not Compound a Drug that appears on the FDA List of Drugs withdrawn or removed from the market for Safety Reasons or on the FDA List of Drug products that present demonstrable difficulties in compounding.
- D. 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/patient/practitioner relationship, and provided that they maintain the prescriptions on file for all such products compounded at the pharmacy as required by the Mississippi Board of Pharmacy.
- E. Pharmacists shall not offer compounded medications to practitioners or other pharmacies for resale. Pharmacies shall not compound medication for practitioners for office administration. Compounding pharmacies/pharmacists may advertise or otherwise promote the fact that they provide prescription compounding services (e.g., chemicals, devices and information when requested); however, they shall not solicit business by promoting to compound specific drug products (e.g., like a manufacturer).
- F. The compounding of inordinate amounts of drugs in anticipation of receiving prescriptions without any historical basis or the distribution of inordinate amounts of compounded products without a patient/practitioner/pharmacist relationship is considered manufacturing.

2. RECORDS AND REPORTS

The pharmacist shall keep records of all compounded products for a period of time as other

prescriptions as required by the Mississippi Board of Pharmacy. Such records shall be readily available for authorized inspection during the retention period at the establishment. These records shall be subject to duplication by photocopying or other means of reproduction as part of any such inspection.

# ARTICLE XXXI COMPOUNDING GUIDELINES

## GOOD-COMPOUNDING-GUIDELINES

The following Good Compounding Practices (GCP's) are meant to apply only to the compounding of medication by pharmacies licensed in the State of Mississippi. Applicable portions of the Pharmacy Practice Act formed the basis for the development of these rules and regulations.

Every compounding facility under the jurisdiction of the MS Board of Pharmacy shall comply with USP 797 and 795 relating to the compounding of pharmaceuticals.

### 1. GENERAL PROVISIONS

- ~~A.~~ These rules and regulations are considered to be the minimum current good compounding practices for the preparation of medications by pharmacists licensed in the State of Mississippi for dispensing and/or administration to humans or animals.
- ~~A.B.~~ Pharmacists engaged in the compounding of drugs shall operate in conformance with applicable law and regulating regulations regarding the practice of pharmacy.
- ~~B.C.~~ 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 that are not commercially available in the marketplace. No compounding and manufacturing shall take place at the same location.
- ~~C.D.~~ Pharmacists shall receive, store, or use drug substances for compounding that meet official compendia requirements, or of a chemical grade in one of the following categories: Chemically Pure (CP), Analytical Reagent (AR), American Chemical Society (ACS), or, if other than this, drug substances which in the professional judgment of the pharmacist are obtained from acceptable and reliable alternatives. A Pharmacist may not Compound a Drug that appears on the FDA List of Drugs withdrawn or removed from the market for Safety Reasons or on the FDA List of Drug products that present demonstrable difficulties in compounding.
- ~~D.E.~~ 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/patient/practitioner relationship, and provided that they maintain the prescriptions on file for all such products compounded at the pharmacy as required by the Mississippi Board of Pharmacy.
- ~~E.F.~~ Pharmacists shall not offer compounded medications to practitioners or other pharmacies for resale; ~~however, practitioners may obtain compounded medications to administer to patients.~~ Pharmacies shall not compound medication for practitioners for office administration. Compounding pharmacies/pharmacists may advertise or otherwise promote the fact that they provide prescription compounding services (e.g., chemicals, devices and information when requested); however, they shall not solicit business by promoting to compound specific drug products (e.g., like a manufacturer).

F.G. The compounding of inordinate amounts of drugs in anticipation of receiving prescriptions without any historical basis or the distribution of inordinate amounts of compounded products without a patient/practitioner/pharmacist relationship is considered manufacturing.

## ~~2. ORGANIZATION AND PERSONNEL~~

- ~~A. Pharmacists engaging in compounding shall maintain proficiency through current awareness and training. Continuing education should include training in the art and science of compounding and the rules and regulations of compounding.~~
- ~~B. Pharmacy technicians may assist the pharmacist in compounding. It is the responsibility of the pharmacist to train and monitor the pharmacy technician. Their duties shall be consistent with the training received.~~
- ~~C. Personnel engaged in the compounding of medications shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons, gowns, hand or arm coverings, or masks shall be worn as necessary to protect personnel from chemical exposure and medication or chemical contamination.~~
- ~~D. Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of the drug compounding operation. Any person shown at any time (either by medical examination or pharmacist determination) to have an apparent illness or open lesions that may adversely affect the safety or quality of a drug product being compounded shall be excluded from direct contact with components, medication containers, closures, in-process materials, and medication products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of the product(s) being compounded. All personnel who assist the pharmacist in compounding procedures shall be instructed to report to the pharmacist any health conditions that may have an adverse effect on drug products.~~

## ~~3. 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 ARTICLE XXVIII of these regulations.~~
- ~~B. 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.~~
- ~~C. Adequate lighting and ventilation shall be provided in all drug compounding areas. Potable water 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 the compounding of drugs shall be maintained in a clean and sanitary condition. It shall be free of infestation by insects, rodents, and other vermin. Trash shall be held and disposed of in a timely and sanitary manner. Sewage and other refuse in and from the pharmacy and immediate medication compounding area(s) shall be disposed of in a safe and sanitary manner.~~
  - E. ~~If sterile products are being compounded, the pharmacist shall follow ARTICLE XXVIII, of these regulations as applicable to the procedure.~~
  - F. ~~If radiopharmaceuticals are being compounded, the pharmacist shall follow ARTICLE XXVII and ARTICLE XXVIII of these regulations as applicable to the procedure.~~
  - G. ~~If drug products with special precautions for 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.~~

#### 4. ~~EQUIPMENT~~

- A. ~~Equipment and utensils used for compounding shall be of appropriate design and appropriate capacity and stored in a manner to protect from contamination. In addition, all equipment and utensils shall be cleaned and sanitized prior to use to prevent contamination that would alter the safety or quality of the drug product beyond that desired. The pharmacist is responsible for determining suitability for use. In the case of sterile compounding, follow ARTICLE XXVIII of these regulations as applicable to equipment and utensils.~~
- B. ~~Automatic, mechanical, electronic or other equipment used in compounding shall be routinely inspected, calibrated (if necessary) or checked to ensure proper performance.~~
- C. ~~It shall be the responsibility of the pharmacist to ensure that the proper container is selected to dispense the finished compounded prescription, whether sterile or non-sterile.~~

#### 5. ~~MEDICATION COMPOUNDING CONTROLS~~

- A. ~~The pharmacist shall ensure that there are formulas and logs maintained either electronically or manually. Formulas shall be comprehensive to include: ingredients, amounts, methodology and equipment, if needed and special information regarding sterile compounding.~~
- B. ~~The pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate at each stage of the compounding procedure to conform to the formula being prepared. Any chemical transferred to a container from the original container shall be labeled with the same information as on the original container and the date of transfer placed on the label.~~
- C. ~~The pharmacist shall establish and conduct procedures so as to monitor the output of compounded prescriptions, i.e., capsule weight variation, adequacy of mixing, clarity~~

~~and pH of solutions and where appropriate procedures to prevent microbial contamination of medications purported to be sterile (refer to ARTICLE XXVIII of these regulations as applicable).~~

~~6. LABELING CONTROL OF EXCESS PRODUCTS~~

- ~~A. The pharmacist shall label any excess compounded product so as to reference it to the formula used and the assigned control number and estimated beyond use date based on the pharmacist's professional judgment, appropriate testing or published data. The product shall be stored appropriately.~~
- ~~B. At the completion of compounding the prescription, the pharmacist shall examine the prescription for correct labeling.~~

2.7. RECORDS AND REPORTS

The pharmacist shall keep records of all compounded products for a period of time as other prescriptions as required by the Mississippi Board of Pharmacy. Such records shall be readily available for authorized inspection during the retention period at the establishment. These records shall be subject to duplication by photocopying or other means of reproduction as part of any such inspection.