

TITLE 30: PROFESSIONS AND OCCUPATIONS

PART 3001: MISSISSIPPI PHARMACY PRACTICE REGULATIONS

**ARTICLE XXVIII REGULATIONS FOR PREPARATION OF STERILE PHARMACEUTICALS**

Every compounding facility under the jurisdiction of the Mississippi Board of Pharmacy shall comply with USP 797 and applicable portions of USP 795.

**DRUG DISTRIBUTION AND CONTROL**

- A. Drug Orders: The pharmacist must receive a written, electronic or verbal order from an authorized prescriber before dispensing any compounded, sterile products. If the drug order is for an inpatient in an institutional facility, a copy of the patient's medication order may serve as an order for the preparation and dispensing of the sterile product. This and the record of administration as recorded on the medication administration record may be maintained as the permanent record in medical records at the facility.

If the drug order is for an outpatient, the order must be in the form of a prescription document or a patient medication order sheet which contains, at a minimum, the following:

- (1) Patient name;
  - (2) Patient address;
  - (3) Name of IV medication and strength and amount of additives;
  - (4) Directions for use;
  - (5) Date;
  - (6) Prescriber's name;
  - (7) Physician's address and Drug Enforcement Administration registration number, if applicable;
  - (8) Refill instructions.
- B. Records required to be maintained: Prescriptions for sterile products shall be filed in accordance with the provisions of ARTICLE XII of these regulations. Patients medication order sheets used as authorization for the dispensing of drugs shall be filed in an easily retrievable manner.

Additionally, a facility which dispenses outpatient prescriptions for sterile products shall produce and maintain a patient profile or medication record system which is separate from the prescription file and/or file of patient medication order sheets. The patient profile or medication record system shall be maintained for a period of two (2) years from the date of the last dispensing. The patient profile or medication record system shall contain, at a minimum:

- (1) Patient's name;
- (2) Date of birth or age;
- (3) Weight;
- (4) Sex;
- (5) Sterile products dispensed;
- (6) Date dispensed;
- (7) Drug content and quantity;
- (8) Patient directions;
- (9) Identifying number;
- (10) Identification of dispensing pharmacist;
- (11) Complete record of other drugs patient is receiving;
- (12) Known drug sensitivities and allergies to drugs and foods;
- (13) Primary diagnosis, chronic conditions.

It shall be the responsibility of the pharmacist-in-charge to ensure that the patient profile or medication record is monitored in accordance with provisions of ARTICLE VIII of these regulations.

## ARTICLE XXVIII REGULATIONS FOR PREPARATION OF STERILE PHARMACEUTICALS

Every compounding facility under the jurisdiction of the Mississippi Board of Pharmacy shall comply with ~~the following regulations relating to the preparation, labeling, and distribution of sterile pharmaceuticals~~ USP 797 and applicable portions of USP 795.

### ~~1. POLICY AND PROCEDURE MANUAL~~

~~Each facility shall develop and maintain a policy and procedure manual. This manual shall be reviewed and revised on an annual basis and be available for inspection by an agent of the Board of Pharmacy. This manual shall include policies and procedures as necessary for:~~

- ~~A. Clinical services;~~
- ~~B. Cytotoxics handling, storage, disposal and spills;~~
- ~~C. Disposal of unused supplies and medications;~~
- ~~D. Drug destruction and returns;~~
- ~~E. Drug dispensing;~~
- ~~F. Drug labeling-relabeling;~~
- ~~G. Drug storage;~~
- ~~H. Duties and qualifications for professional and non professional staff;~~
- ~~I. Equipment;~~
- ~~J. Handling of infectious wastes;~~
- ~~K. Infusion devices and drug delivery systems;~~
- ~~L. Investigational drugs;~~
- ~~M. Obtaining a protocol on investigational drugs from the principal investigator;~~
- ~~N. Public safety;~~
- ~~O. Quality assurance procedures to include:
  - ~~(1) Recall procedures;~~
  - ~~(2) Storage and dating;~~
  - ~~(3) Educational procedures for professional staff, non professional staff and patient;~~
  - ~~(4) Sterile procedures to include a record of the routine maintenance and report of hood certification;~~
  - ~~(5) Sterility testing.~~~~
- ~~P. Record keeping;~~

~~Q. Reference materials;~~  
~~R. Sanitation;~~  
~~S. Security;~~  
~~T. Sterile product preparation procedures;~~  
~~U. Transportation.~~

In facilities permitted by the Mississippi Board of Pharmacy the Policy and Procedure Manual shall, except in emergency situations, require that all sterile pharmaceuticals be prepared using the appropriate hood. Such hood shall be inspected and certified at least annually by a qualified technician.

## 2. PHYSICAL REQUIREMENTS

### A. Space:

The facility shall have a designated area with entry restricted to designated personnel for preparing compounded sterile products. This area shall be designed to avoid unnecessary traffic and airflow disturbances from activity within the facility. This designated area shall be used only for the preparation of these specialty products. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

### B. Equipment:

The facility shall have:

- (1) Appropriate environmental control devices capable of maintaining at least Class 100 conditions in the work space where critical objects are exposed and critical activities are performed; furthermore, these devices are capable of maintaining Class 100 conditions during normal activity. Examples of appropriate devices include laminar airflow hoods and zonal laminar flow of HEPA filtered air;
- (2) Sink with hot and cold running water which is convenient to the compounding area for the purpose of hand scrubs prior to compounding;
- (3) Appropriate disposal containers for used needles, syringes, etc., and if applicable for cytotoxic waste from the preparation of chemotherapy agents, and infectious wastes;
- (4) When cytotoxic drug products are prepared, appropriate environmental control also includes appropriate biohazard cabinetry;
- (5) Refrigerator/Freezer with a thermometer;
- (6) Appropriate delivery container including temperature controlled container when needed;
- (7) Infusion devices, if appropriate.

### C. Supplies:

The facility shall maintain:

- (1) Disposable needles, syringes, and other supplies needed for aseptic admixture;
- (2) Disinfectant cleaning solutions;
- (3) Hand washing agent with germicidal action;
- (4) Disposable, lint free towels or wipes;
- (5) Appropriate filters and filtration equipment;
- (6) Disposable masks, caps, gown, and sterile disposable gloves if applicable.

### D. Security:

~~The facility shall provide adequate security for all drugs and shall comply with requirements of other ARTICLES of these regulations relative to security on controlled substances.~~

~~E. Reference Library:~~

~~The facility shall have adequate reference materials related to the preparation, labeling, and distribution of sterile products. Some suggested sources include:~~

~~Handbook on Injectable Drugs (ASHP)  
King's Guide to Parenteral Admixtures  
USP/NF  
American Hospital Formulary Service  
Procedures for Handling Cytotoxic Drugs (ASHP)~~

~~The pharmacy shall have copies of applicable state and federal laws and OSHA requirements.~~

~~3. PERSONNEL~~

- ~~A. Pharmacist In Charge: Each facility shall be supervised by a pharmacist who is licensed to practice pharmacy in this state and who is knowledgeable in the specialized functions of preparing and dispensing compounded, sterile pharmaceuticals, including the principles of aseptic technique and quality assurance. This knowledge may be obtained through residency training programs, continuing education programs, or experience in an IV admixture facility. The pharmacist in charge shall be responsible for the purchasing, storage, compounding, repackaging, dispensing, and distribution of all drugs and pharmaceuticals. He/she shall also be responsible for the development and continuing review of all policies and procedures, training manuals, and the quality assurance programs, as well as participation in those aspects of the facility's patient care evaluation program relating to pharmaceutical material utilization and effectiveness. The pharmacist in charge may be assisted by additional pharmacists adequately trained in this area of practice.~~
- ~~B. Pharmacy Technicians: The pharmacist in charge may be assisted by pharmacy technicians. The duties and responsibilities of these personnel must be consistent with their training and experience.~~
- ~~C. Staffing: A pharmacist shall be accessible at all times at each facility to respond to patients and other health professionals questions and needs.~~

~~4. DRUG DISTRIBUTION AND CONTROL~~

- ~~A. Drug Orders: The pharmacist must receive a written, electronic or verbal order from an authorized prescriber before dispensing any compounded, sterile products. If the drug order is for an inpatient in an institutional facility, a copy of the patient's medication order may serve as an order for the preparation and dispensing of the sterile product. This and the record of administration as recorded on the medication administration record may be maintained as the permanent record in medical records~~

~~at the facility. Sterile products prepared for inpatient administration shall be labeled, stored and delivered in accordance with written policy and procedure which comply with all requirements of The Joint Commission on Accreditation of Health Care Organizations or the Mississippi State Department of Health.~~

If the drug order is for an outpatient, the order must be in the form of a prescription document or a patient medication order sheet which contains, at a minimum, the following:

- (1) Patient name;
- (2) Patient address;
- (3) Name of IV medication and strength and amount of additives;
- (4) Directions for use;
- (5) Date;
- (6) Prescriber's name;
- (7) Physician's address and Drug Enforcement Administration registration number, if applicable;
- (8) Refill instructions.

- B. Records required to be maintained: Prescriptions for sterile products shall be filed in accordance with the provisions of ARTICLE XII of these regulations. Patients medication order sheets used as authorization for the dispensing of drugs shall be filed in an easily retrievable manner.

Additionally, a facility which dispenses outpatient prescriptions for sterile products shall produce and maintain a patient profile or medication record system which is separate from the prescription file and/or file of patient medication order sheets. The patient profile or medication record system shall be maintained for a period of two (2) years from the date of the last dispensing. The patient profile or medication record system shall contain, at a minimum:

- (1) Patient's name;
- (2) Date of birth or age;
- (3) Weight;
- (4) Sex;
- (5) Sterile products dispensed;
- (6) Date dispensed;
- (7) Drug content and quantity;
- (8) Patient directions;
- (9) Identifying number;
- (10) Identification of dispensing pharmacist;
- (11) Complete record of other drugs patient is receiving;
- (12) Known drug sensitivities and allergies to drugs and foods;
- (13) Primary diagnosis, chronic conditions.

It shall be the responsibility of the pharmacist-in-charge to ensure that the patient profile or medication record is monitored in accordance with provisions of ARTICLE VIII of these regulations.

- ~~C. Labeling: Each sterile pharmaceutical dispensed for an outpatient shall bear a label~~

with the following information:

- (1) Name and address of the facility;
- (2) Date and identifying number;
- (3) Patient's name;
- (4) Name of medication and strength, and amount of additives;
- (5) Directions for use, including infusion rate;
- (6) Prescriber's name;
- (7) Date of compounding;
- (8) Expiration date and time;
- (9) Identity of pharmacist responsible for compounding and dispensing;
- (10) Storage requirements;
- (11) Auxiliary labels, where applicable.

- D. ~~Storage and Delivery: The pharmacist in charge shall be responsible for the proper storage in the pharmacy of all sterile pharmaceuticals after they are compounded. It shall be the responsibility of the pharmacist in charge to assure that all sterile pharmaceuticals dispensed as outpatient prescriptions are shipped or delivered to the patient in appropriate temperature-controlled (as defined by USP Standards) delivery containers and stored appropriately in the patient's home. The pharmacist in charge shall also be responsible for security on controlled substance prescriptions until delivered to the patient's home.~~
- E. ~~Disposal of Infectious Wastes: The pharmacist in charge is responsible for assuring that there are written policies and procedures for safe collection and disposal of any medical or infectious waste resulting from the dispensing of sterile products. These policies and procedures shall extend to any location where sterile products are administered.~~

## 5. ~~CYTOTOXIC MEDICATION~~

- A. ~~Additional Requirements: To insure the protection of personnel involved, the pharmacist in charge shall assure that the following requirements are met in facilities that prepare cytotoxic medications;~~
- (1) ~~All cytotoxic medications should be compounded in a vertical flow, Class II, biological safety cabinet;~~
  - (2) ~~Disposal of cytotoxic waste shall comply with all applicable local, state and federal requirements;~~
  - (3) ~~Prepared doses of cytotoxic medications must be dispensed, labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.~~