TITLE 30: PROFESSIONS AND OCCUPATIONS
PART 3001: MISSISSIPPI PHARMACY PRACTICE REGULATIONS

ARTICLE XXXI COMPOUNDING GUIDELINES

Every pharmacy permitted by the Mississippi Board of Pharmacy engaged in the compounding of pharmaceuticals that is not a licensed 503B pharmacy following good manufacturing practices (GMP) shall comply with USP 795, USP 797, and USP 800 when compounding in the scope of those chapters. The designated facility USP representative must be a pharmacist licensed in the State of Mississippi.

1. GENERAL PROVISIONS
   - A. Prior to engaging in the compounding of pharmaceuticals, a pharmacy shall obtain a compounding certificate from the Mississippi Board of Pharmacy.
     - i. To obtain a compounding certificate, an applicant must complete a compounding certificate application.
     - ii. A compounding certificate will expire when the pharmacy permit expires and can be renewed at the time a pharmacy permit is renewed.
     - iii. Compounding, without obtaining the compounding certificate, shall be grounds for disciplinary action.
     - iv. Every pharmacy that engages in compounding shall submit a compounding statistical report to the Board on or about January 31st of each year on a form prescribed by the Board.
     - v. Failure to submit the report as required by this regulation shall be grounds for disciplinary action.
     - vi. A compounding certificate shall become inactive if a pharmacy fails to compound any prescriptions in a calendar year. A pharmacy may not compound prescriptions with an inactive compounding certificate. A pharmacy may petition the Board to activate a compounding certificate that is inactive.
     - vii. Any pharmacy with an active compounding certificate is subject to a compounding inspection by the Board.
   - 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, a pharmacy may compound, for an individual patient, medications that are not commercially available in the marketplace. Compounding and manufacturing, as defined within the regulations, are not permitted in the same facility. A pharmacy may not Compound a Drug that appears on the FDA List of Drugs withdrawn or removed from the market for Safety Reasons or on the FDA List of Drug products that present demonstrable difficulties in compounding.
   - C. For the purpose of this Article, flavoring is not considered compounding. In addition, the combining of commercially manufactured, ready- to-use products shall be exempt from USP 795 compounding standards under the following conditions:
     - i. No more than four (4) commercially manufactured ready-to-use products (that have not been manipulated) are used;
     - ii. Compounding is not done in anticipation of medication orders;
     - iii. Must follow USP 795 beyond use dates (BUDs);
     - iv. A valid prescription shall serve as the compounding record;

v. The prescription label shall comply with all related USP chapter requirements as well as the labeling requirements as set forth in Article XIV of these regulations.

D. A pharmacy 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. Pharmacies shall not offer compounded human drug products to practitioners or to other pharmacies for resale or dispensing. However, patient specific medications may be prepared on behalf of a pharmacy permitted as an Institutional I, Hospital, 3.1 pharmacy for an inpatient at that facility. Pharmacies may compound patient specific medications for office administration by a practitioner.

F. Compounding pharmacies 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).

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. RECORDS

A. The pharmacy shall keep records of all compounded products 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.

B. Drug Orders: The pharmacist must receive a written, electronic or verbal order from an authorized prescriber before dispensing any compounded product.

i. If the drug order is for an inpatient at an institutional facility, a copy of the patient's medication order may serve as an order for the preparation and dispensing of the compounded product. This and the medication administration record may be maintained as the permanent record in medical records at the facility.

ii. 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 medication and strength;
(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.

C. Prescriptions for compounded products shall be filed in accordance with the prescription recordkeeping provisions of these regulations. Patient medication order sheets used as authorization for the dispensing of drugs shall be filed in an easily retrievable manner.

3. COMPOUNDING WHEN COMMERCIAL PRODUCTS ARE NOT AVAILABLE

A. A pharmacy may prepare a copy of a commercial product when that commercial product is not available as evidenced by either of the following:
    i. Products that appear as unresolved status on the FDA drug shortage list in effect under section 506E of the FD&C Act; or
    ii. Products discontinued and no longer marketed by the manufacturer.

4. COMPOUNDING FOR VETERINARY USE

A. All compounding for non-human medications must follow USP 795/797/800 compounding standards.
B. A pharmacy may compound a preparation intended for administration to an animal patient:
    i. Pursuant to a patient specific prescription; or
    ii. Pursuant to a non-patient specific order from a veterinarian.
C. The label for non-patient specific compounded preparations shall contain, at a minimum, the following:
    i. Pharmacy's name, address and telephone number;
    ii. Veterinarian's name;
    iii. Name of preparation;
    iv. Strength and concentration;
    v. Lot number;
    vi. Beyond use date (BUD);
    vii. Special storage requirements, if applicable;
    viii. Name or initials of the pharmacist responsible for final check of the preparation.

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      ii. Compounding is not done in anticipation of medication orders;
      iii. Must follow USP 795 beyond use dates (BUDs);
      iv. A valid prescription shall serve as the compounding record;

v. The prescription label shall comply with all related USP chapter requirements as well as the labeling requirements as set forth in Article XIV of these regulations. ~~and also include:~~

~~1. Name of Preparation;~~
~~2. Strength and concentration of each component;~~
~~3. Beyond Use Date;~~
~~4. Special storage requirements, if applicable; and~~
~~5. Cautionary auxiliary labels, if applicable.~~

D. A pharmacy 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.

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3. name of medication and strength;

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   ii. Products ~~temporarily unavailable~~ discontinued and no longer marketed by from the manufacturer, ~~as documented by invoice or other communication from the distributor or manufacturer.~~

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