

**Louisiana Administrative Code**

**Title 46 – Professional and Occupational Standards**

**Part LIII: Pharmacists**

**Chapter 25. Prescriptions, Drugs, and Devices**

**Subchapter C. Compounding of Drugs**

**§2531. Purpose and Scope**

- A. Purpose. The rules of this Subchapter describe the requirements of minimum current good compounding practices for the preparation of drug formulations by Louisiana-licensed pharmacists, pharmacy interns, pharmacy technicians, and pharmacy technician candidates for dispensing and/or administration to patients.
- B. Scope. These requirements are intended to apply to all compounded preparations and pharmacy-generated drugs, sterile and non-sterile, regardless of the location of the patient, e.g., home, hospital, nursing home, hospice, or physician’s office.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2105 (October 2003), effective January 1, 2004, amended LR

**§2533. Definitions**

- A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section:
  - ...
    - 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 or labeling or relabeling of its container, and the promotion and marketing of such drugs or devices. Manufacturing also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons.
    - Pharmacy-generated Drug* – a drug made by a pharmacy.
    - Preparation* – a compounded drug dosage form or dietary supplement or a device to which a compounder has introduced a drug. This term will be used to describe compounded formulations; the term *product* will be used to describe manufactured pharmaceutical dosage forms.
    - ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2105 (October 2003), effective January 1, 2004, amended LR

**§2535. General Standards**

- A. Compounding Practices. Compounded medications may be prepared using prescription medications, over-the-counter medications, chemicals, compounds, or other components.
  - 1. A pharmacy shall have written procedures as necessary for the compounding of drug preparations and the making of pharmacy-generated drugs to assure that the finished

- 53 preparations and products have the identity, strength, quality, and purity they are represented  
54 to possess.
- 55 2. All drug preparation activities shall be accomplished utilizing accepted pharmacy techniques,  
56 practices, and equipment.
- 57 a. The compounding of sterile preparations pursuant to the receipt of a patient-  
58 specific prescription shall comply with the provisions of USP Chapter 797.
- 59 b. The compounding of non-sterile preparations pursuant to the receipt of a patient-  
60 specific prescription shall comply with the provisions of USP Chapter 795.
- 61 c. Subject to the allowance provided in Paragraph D of this Section, the making of  
62 pharmacy-generated drugs pursuant to the receipt of a non patient-specific  
63 practitioner's order shall comply with the provisions of the *Current Good*  
64 *Manufacturing Practices*, as published in 21 CFR 211 or its successor.
- 65 3. Products or duplicates of products removed from the market for the purposes of safety shall  
66 not be used to compound prescriptions for human use.
- 67 B. Board Notification. An applicant or pharmacy permit holder who wishes to engage in the  
68 compounding of sterile preparations or generating sterile drugs shall notify the board and shall receive  
69 approval from the board prior to beginning that practice.
- 70 C. Training and Education. All individuals compounding sterile preparations and generating sterile drugs  
71 shall:
- 72 1. Obtain practical and/or academic training in the preparation of sterile drugs;
- 73 2. Complete a minimum of one hour of Accreditation Council for Pharmacy Education (ACPE)  
74 or board-approved continuing education, on an annual basis, related to sterile drug  
75 preparation, dispensing, and utilization;
- 76 3. Use proper aseptic technique in all sterile product preparation as defined by the pharmacy  
77 practice site's policy and procedure manual;
- 78 4. Qualify through an appropriate combination of specific training and experience to operate or  
79 manipulate any item of equipment, apparatus, or device to which such persons will be  
80 assigned to use to make and dispense sterile preparations and products; and
- 81 5. Maintain in the pharmacy practice site a written record of initial and subsequent training and  
82 competency evaluations. The record shall contain the following minimum information:
- 83 a. name of the individual receiving the training/evaluation;
- 84 b. date of the training/evaluation;
- 85 c. general description of the topics covered;
- 86 d. signature of the individual receiving the training/evaluation; and
- 87 e. name and signature of the individual providing the training/evaluation.
- 88 D. Pharmacy-generated Drug. Pharmacists may prepare pharmacy-generated drugs for a practitioner's  
89 use with the following requirements:
- 90 1. an order from the practitioner indicating the formula and quantity ordered to be made by the  
91 pharmacy;
- 92 2. the product is to be administered by the practitioner and not dispensed to the patient;
- 93 3. the pharmacist shall generate a label for the product which complies with the requirements of  
94 Paragraph G of this Section; and
- 95 4. a pharmacy may prepare such drugs in compliance with the compounding standards in USP  
96 Chapter 795 for non-sterile preparations or USP Chapter 797 for sterile preparations, provided  
97 such drugs made according to these standards shall not exceed ten percent of the total number  
98 of prescriptions dispensed and orders distributed by the pharmacy on an annual basis.
- 99 a. The purpose of this limitation is to ensure at least ninety percent of the total  
100 number of prescriptions and orders released from the pharmacy on an annual basis  
101 shall be dispensed pursuant to patient-specific prescriptions, and further, no more  
102 than ten percent shall be distributed pursuant to non patient-specific orders from a  
103 practitioner.
- 104 b. With respect to Louisiana-licensed non-resident pharmacies, the ten percent  
105 limitation shall be calculated from the total number of prescriptions and orders  
106 sent to Louisiana residents and/or clients.

- 107 c. No pharmacy shall distribute any pharmacy-generated drug products to a state  
108 other than the state within which the pharmacy is located.
- 109 5. The pharmacy shall label any pharmacy-generated drug product held in the pharmacy so as to  
110 reference it to the formula used and the assigned lot number and estimated beyond use date  
111 based on the pharmacist's professional judgment and/or other appropriate testing or published  
112 data.
- 113 6. The pharmacy shall establish and maintain a record of practitioners receiving pharmacy-  
114 generated drugs. Such records shall contain, at a minimum, the name of the practitioner, the  
115 name of the drug, the lot number of the drug, and the date of formulation of the drug.
- 116 E. Anticipated Use Preparations. The pharmacist shall label any excess compounded preparation so as to  
117 reference it to the formula used and the assigned lot number and estimated beyond use date based on  
118 the pharmacist's professional judgment and/or other appropriate testing or published data.
- 119 F. Compounding Commercial Products Not Available  
120 A pharmacy may prepare a copy of a commercial product when that product is not available as  
121 evidenced by either of the following:
- 122 1. Products appearing on a website maintained by the federal Food and Drug Administration  
123 (FDA) and/or the American Society of Health-System Pharmacists (ASHP).
- 124 2. Products temporarily unavailable from manufacturers, as documented by invoice or other  
125 communication from the distributor or manufacturer.
- 126 G. Labeling of Compounded Preparations and Pharmacy-generated Drugs.
- 127 1. For patient-specific compounded preparations, the labeling requirements of R.S. 37:1225, or  
128 its successor, as well as this Chapter, shall apply.
- 129 2. All pharmacy-generated drugs shall be packaged in a suitable container with a label  
130 containing, at a minimum, the following information:
- 131 a. pharmacy's name, address, and telephone number;
- 132 b. practitioner's name;
- 133 c. name of preparation;
- 134 d. strength and concentration;
- 135 e. lot number;
- 136 f. beyond use date;
- 137 g. special storage requirements, if applicable;
- 138 h. assigned identification number; and
- 139 i. pharmacist's name or initials.
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141 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

142 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708  
143 (October 1988), effective January 1, 1989, amended LR 23:1316 (October 1997), amended LR 29:2105 (October  
144 2003), effective January 1, 2004, amended LR 39: 236 (Emergency Rule effective January 31, 2013), amended LR  
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146 **§2537. Requirements for Compounding and Generating Sterile Preparations and Products**  
147 Repealed.

148  
149 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

150 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708  
151 (October 1988), effective January 1, 1989, amended LR 29:2106 (October 2003), effective January 1, 2004, repealed  
152 LR