

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 25. Prescriptions, Drugs, and Devices

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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, sterile and non-sterile, regardless of the location of the patient, e.g., home, hospital, nursing home, hospice, or practitioner’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:
 - ...
 - 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.
 - ...

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 to assure that the finished preparations have the identity, strength, quality, and purity they are represented to possess.
 - 2. All compounding activities shall be accomplished utilizing accepted pharmacy techniques, practices, and equipment, as well as the Federal Food, Drug & Cosmetic Act (FDCA), Title 21 of the Code of Federal Regulations (CFR), and all relevant chapters of the United States Pharmacopeia (USP).
 - a. The compounding of sterile preparations pursuant to the receipt of a patient-specific prescription shall comply with the provisions of Section 503A of the FDCA and USP Chapter 797.

- 53 b. The compounding of non-sterile preparations pursuant to the receipt of a patient-
54 specific prescription shall comply with the provisions of Section 503A of the
55 FDCA and USP Chapter 795.
56 c. The compounding of preparations for veterinary use shall comply with the
57 provisions of 21 CFR 530.
58 d. The compounding of positron emission tomography (PET) drugs shall comply
59 with the provisions of 21 CFR 212.
60 3. Products or duplicates of products removed from the market for the purposes of safety shall
61 not be used to compound prescriptions for human use.
62 B. Board Notification. An applicant or pharmacy permit holder who wishes to engage in the
63 compounding of sterile preparations shall notify the board and shall receive approval from the board
64 prior to beginning that practice.
65 C. Training and Education. All individuals compounding sterile preparations shall:
66 1. Obtain practical and/or academic training in the compounding and dispensing of sterile
67 preparations;
68 2. Complete a minimum of one hour of Accreditation Council for Pharmacy Education (ACPE)
69 accredited or board-approved continuing education, on an annual basis, related to sterile drug
70 preparation, dispensing, and utilization;
71 3. Use proper aseptic technique in compounding of all sterile preparations, as defined by the
72 pharmacy practice site's policy and procedure manual;
73 4. Qualify through an appropriate combination of specific training and experience to operate or
74 manipulate any item of equipment, apparatus, or device to which such persons will be
75 assigned to use to make and dispense sterile preparations; and
76 5. Maintain in the pharmacy practice site a written record of initial and subsequent training and
77 competency evaluations. The record shall contain the following minimum information:
78 a. name of the individual receiving the training/evaluation;
79 b. date of the training/evaluation;
80 c. general description of the topics covered;
81 d. signature of the individual receiving the training/evaluation; and
82 e. name and signature of the individual providing the training/evaluation.
83 D. Anticipated Use Preparations. The pharmacist shall label any excess compounded preparation so as to
84 reference it to the formula used and the assigned lot number and estimated beyond use date based on
85 the pharmacist's professional judgment and/or other appropriate testing or published data.
86 E. Compounding Commercial Products Not Available
87 A pharmacy may prepare a copy of a commercial product when that product is not available as
88 evidenced by either of the following:
89 a. Products appearing on a website maintained by the federal Food and Drug Administration
90 (FDA) and/or the American Society of Health-System Pharmacists (ASHP).
91 b. Products temporarily unavailable from manufacturers, as documented by invoice or other
92 communication from the distributor or manufacturer.
93 F. Labeling of Compounded Preparations.
94 a. The labeling requirements of R.S. 37:1225, or its successor, as well as this Chapter, shall
95 apply.
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97 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

98 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
99 (October 1988), effective January 1, 1989, amended LR 23:1316 (October 1997), amended LR 29:2105 (October
100 2003), effective January 1, 2004, amended LR

102 **§2537. Requirements for Compounding Sterile Products**

103 Repealed.

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

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