

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 25. Prescriptions, Drugs, and Devices

Subchapter C. Compounding of Drugs

§2535. General Standards

A. Compounding Practices. Compounded medications may be prepared using prescription medications, over-the-counter medications, chemicals, compounds, or other components.

1. ...

2. All compounding shall be accomplished utilizing accepted pharmacy techniques, practices, and equipment, as well as the Federal Food, Drug and Cosmetic Act of 1938 as subsequently amended, most recently in November 2013 (FDCA), the 2014 edition of Title 21 of the *Code of Federal Regulations (CFR)*, and all relevant chapters of the 2014 edition of the United States Pharmacopeia-National Formulary (USP 37 – NF 32).

a. The compounding of sterile preparations pursuant to the receipt of a patient-specific prescription shall comply with the provisions of Section 503-A of the FDCA and USP Chapter 797.

b. The compounding of non-sterile preparations pursuant to the receipt of a patient-specific prescription shall comply with the provisions of Section 503-A of the FDCA and USP Chapter 795.

c. The compounding of preparations for veterinary use shall comply with the provisions of Section 530 of Title 21 of the CFR.

d. The compounding of positron emission tomography (PET) drugs shall comply with the provisions of Section 212 of Title 21 of the CFR.

3. ...

B. Board Notification. ...

C. Training and Education. ...

D. Anticipated Use Preparations. ...

E. Veterinarian Administered Compounds, also referred to as Pharmacy-Generated Drugs

1. Upon receipt of a valid non-patient-specific medical order from a licensed veterinarian, the pharmacy may compound a preparation intended for administration to an animal patient by the veterinarian.

2. These preparations may not be distributed to any other third party by the pharmacy, nor may these preparations be further re-sold or distributed by the veterinarian ordering the preparation from the pharmacy.

3. This authorization is primarily intended to facilitate the preparation of medications needed for emergency use in a veterinary office practice. Given the limited application of this authorization, which allows these products to be prepared using less rigorous standards applicable to compounding as opposed to the more rigorous standards applicable to manufacturing processes, the compounding pharmacy preparing these products shall be limited in the amount of such products they can prepare.

- 51 a. No Louisiana-licensed pharmacy may distribute any amount of practitioner
- 52 administered compounds in excess of five percent of the total amount of drug
- 53 products dispensed and/or distributed from their pharmacy.
- 54 b. The five percent limitation shall be calculated on a monthly basis and shall reference
- 55 the number of dosage units.
- 56 c. For those Louisiana-licensed pharmacies located outside Louisiana, the total amount
- 57 distributed and/or dispensed shall reference the pharmacy's total business within the
- 58 state of Louisiana.

59 ~~E. F.~~ Compounding Commercial Products not Available. ...

60 ~~F. G.~~ Labeling of Compounded Preparations.

- 61 1. For patient-specific compounded preparations, the labeling requirements of R.S. 37:1225, or
- 62 its successor, as well as §2527 of this Chapter, or its successor shall apply.
- 63 2. For veterinarian administered compounds, the label shall contain, at a minimum, the
- 64 following data elements:
 - 65 a. pharmacy's name, address, and telephone number;
 - 66 b. veterinarian's name;
 - 67 c. name of preparation;
 - 68 d. strength and concentration;
 - 69 e. lot number;
 - 70 f. beyond use date;
 - 71 g. special storage requirements, if applicable;
 - 72 h. identification number assigned by the pharmacy; and
 - 73 i. name or initials of pharmacist responsible for final check of the preparation.

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

76 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708

77 (October 1988), effective January 1, 1989, amended LR 23:1316 (October 1997), amended LR 29:2105 (October

78 2003), effective January 1, 2004, amended LR 41:97 (January 2015), amended LR

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