

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~~ 2016 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 4. The provisions of this Paragraph E notwithstanding, pharmacists intending to engage in the
 60 compounding of veterinary preparations pursuant to non-patient-specific medical orders from
 61 veterinarians should be aware that federal law or rule may not permit such activity by a
 62 licensed pharmacy, and further, such pharmacists should be aware that the board's rules
 63 cannot legitimize an activity that is not permitted under federal law or rule, and further, such
 64 pharmacists should be aware that while this activity is permitted by the board, pharmacists
 65 engaging in this activity remain subject to the full force and effect of federal law enforcement.
 66 ~~E. F.~~ Compounding Commercial Products not Available. ...
 67 ~~F. G.~~ Labeling of Compounded Preparations.
 68 1. For patient-specific compounded preparations, the labeling requirements of R.S. 37:1225, or
 69 its successor, as well as §2527 of this Chapter, or its successor shall apply.
 70 2. For veterinarian administered compounds, the label shall contain, at a minimum, the
 71 following data elements:
 72 a. pharmacy's name, address, and telephone number;
 73 b. veterinarian's name;
 74 c. name of preparation;
 75 d. strength and concentration;
 76 e. lot number;
 77 f. beyond use date;
 78 g. special storage requirements, if applicable;
 79 h. identification number assigned by the pharmacy; and
 80 i. name or initials of pharmacist responsible for final check of the preparation.
 81

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

83 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708
 84 (October 1988), effective January 1, 1989, amended LR 23:1316 (October 1997), amended LR 29:2105 (October
 85 2003), effective January 1, 2004, amended LR 41:97 (January 2015), amended LR
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87 ...
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