Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 25. Prescriptions, Drugs, and Devices

§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 shall be accomplished utilizing accepted pharmacy techniques, practices, and equipment, and in compliance with the Federal Food, Drug and Cosmetic Act of 1938 (FDCA) as subsequently amended, the current 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. Products or duplicates of products removed from the market for the purposes of safety shall not be used to compound prescriptions for human use.

B. Board Notification. An applicant or pharmacy permit holder who wishes to engage in the compounding of sterile preparations shall notify the board and shall receive approval from the board prior to beginning that practice.

C. Training and Education. All individuals compounding sterile preparations shall:

1. obtain practical and/or academic training in the compounding and dispensing of sterile preparations;
2. complete a minimum of one hour of Accreditation Council for Pharmacy Education (ACPE) accredited or board-approved continuing education, on an annual basis, related to sterile drug preparation, dispensing, and utilization;
3. use proper aseptic technique in compounding of all sterile preparations, as defined by the pharmacy

practice site's policy and procedure manual;

4. qualify through an appropriate combination of specific training and experience to operate or manipulate any item of equipment, apparatus, or device to which such persons will be assigned to use to make and dispense sterile preparations; and
5. maintain in the pharmacy practice site a written record of initial and subsequent training and competency evaluations. The record shall contain the following minimum information:
   a. name of the individual receiving the training/evaluation;
   b. date of the training/evaluation;
   c. general description of the topics covered;
   d. signature of the individual receiving the training/evaluation; and
   e. name and signature of the individual providing the training/evaluation.

D. Anticipated Use Preparations. The pharmacist shall label any excess compounded preparation so as to reference it to the formula used and the assigned lot number and estimated beyond use date based on the pharmacist's professional judgment and/or other appropriate testing or published data.

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 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 medication 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 appliable to manufacturing processes, the compounding pharmacy preparing these products shall be limited in the amount of such products they can prepare.
   a. No Louisiana-licensed pharmacy may distribute any amount of practitioner administered compounds in excess of five percent of the total amount of drug products dispensed and/or distributed from their pharmacy.
   b. The five percent limitation shall be calculated on a monthly basis and shall reference the number of dosage units.
   c. For those Louisiana-licensed pharmacies located outside Louisiana, the total amount distributed and/or dispensed shall reference the pharmacy's total business within the state of Louisiana.
4. The provisions of this Subsection E notwithstanding, pharmacists intending to engage in the compounding of veterinary preparations pursuant to non-patient-specific medical orders from veterinarians should be aware that federal law or rule may not permit such activity by a licensed pharmacy, and further, such pharmacists should be aware that the board's rules cannot legitimize an activity that is not permitted under federal law or rule, and further, such pharmacists should be aware that

while this activity is permitted by the board, pharmacists engaging in this activity remain subject to the full force and effect of federal law enforcement.

F. Compounding Copies of Commercial Drug Products.

1. Copies of commercial drug products contain the same active pharmaceutical ingredient(s) in the same , similar, or easily substitutable dosage strength which can be used by the same route of administration. Changes in strength of less than 10 percent from the commercial drug product shall not be considered significant enough to warrant the preparation of a copy of a commercial drug product. In the event a prescriber determines a change in the formulation of a commercial drug product is necessary to produce a significant clinical difference for the patient and that determination is documented on the prescription, the pharmacy may prepare a variation of the commercial drug product, provided:
   a. the prescriber's determination shall identify both the relevant change requested and the clinically significant difference the change will produce for the patient; and
   b. the pharmacy does not prepare copies of commercial drug products regularly or in inordinate amounts.
2. A pharmacy may prepare a copy of a commercial drug product when that product has been discontinued and is no longer marketed, or the product appears on the drug shortage list maintained by the federal Food and Drug Administration, or the product is temporarily unavailable as demonstrated by invoice or other communication from the distributor or manufacturer.

G. Labeling of Compounded Preparations.

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

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 23:1316 (October 1997), LR 29:2105 (October 2003), effective January 1, 2004, LR 41:97 (January 2015), amended by the Department of Health, Board of Pharmacy, LR 42:891 (June 2016), LR 46:577 (April 2020).