

RULE

**Department of Health
Board of Pharmacy**

Pharmacy Compounding (LAC 46:LIII.2535)

In accordance with the provisions of the Administrative Procedure Act (R.S. 49:950 et seq.) and the Pharmacy Practice Act (R.S. 37:1161 et seq.), the Louisiana Board of Pharmacy has amended the section of its rules containing standards for pharmacy compounding. The amendment of Paragraph A.2 updates the references to federal law and rule. The amendment of Subsection F updates the standards for compounding copies of commercially available products consistent with recent guidance information from the federal Food and Drug Administration. This Rule is hereby adopted on the day of promulgation.

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. ...

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 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.2.a. - E.4. ...

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 ten 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. - G.2.i. ...

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), amended LR 29:2105 (October 2003), effective January 1, 2004, amended LR 41:97 (January 2015), amended LR 42:891 (June 2016), LR 46:577 (April 2020).

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